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13. ABSTRACT ***(Maximum 200 Words)***

There currently is no accepted credentialing or certification process for the many inexperienced clinicians beginning to perform Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB). The work being funded by this grant is designed to establish quality assurance (QA) guidelines for the conduct of TIPPB for the purpose of performing national, multi- institutional cooperative studies. The guidelines are intended to: (1) ensure that participating institutions have the proper equipment and appropriate procedures in place to administer TIPPB; (2) define a standard TIPPB data set to be submitted to the 3DQA Center for each treated patient to assess protocol compliance; (3) define an electronic data exchange mechanism for submission of each protocol patient's digital data set; and (4) establish a QA review process of the submitted data. Substantial progress has been made in establishing a methodology for electronic data exchange. A proposed credentialing process and QA guidelines have been developed. Work is in progress in modifying a CMS FOCUS 3DRTP system to serve as a TIPPB QA review station. Work will begin in the next funding period on the development of remote QA review tools and a national database for the TIPPB treatment planning data that can be linked with clinical outcome data.

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JA Purdy Sep 27, 1999

PI - Signature Date

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INTRODUCTION

Although local treatment of early prostate cancer by external beam radiation therapy or surgery has been somewhat successful, local recurrence, metastases and the morbidity of treatment remain substantial problems limiting the complication-free cure rate of this very common disease. Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB) is being selected by a rapidly increasing proportion of patients as the solution to the problems associated with radiation therapy and surgery. TIPPB is technically challenging. Achieving a tumorcidal dose throughout the entire gland is believed to be an important goal in total tumor eradication (TTE) and in practice is difficult to achieve. Although the procedure has shown good results in the hands of experienced teams, there remains no accepted credentialing or certification process for the many inexperienced clinicians beginning to perform TIPPB. This funded effort is designed to address this need in anticipation of future prospective clinical trials. Specifically, over the course of this grant, the RTOG 3D Quality Assurance (QA) Center plan to complete the 5 tasks listed below:

Task 1. Develop and evaluate analytical methods and tools for three-dimensional calculation and dose volume histogram evaluation of prostate brachytherapy (months 1-24).
   a. Review published recommendations, data from RTOG 98-05, data from any multi-institutional pilot studies, and other data sets to determine current standards of care.
   b. Implement 3D dose calculation and dose volume histogram evaluation tool for prostate brachytherapy.
   c. Establish a set of parameters which can be effectively used to quantify implant quality.
   d. Test the proposed criteria against sample data from RTOG 98-05 as well as other data
   sources.
   e. Evaluate commercial systems as to their ability to provide a similar or enhanced analysis.

Task 2. Establish a methodology for electronic data exchange of treatment planning verification data between institutions and the 3D QA Center as well as the RTOG Statistical Headquarters (months 1-18).
   a. Use existing 3D QA Center and RTOG expertise to develop file formats and transfer protocols similar to those currently used by the RTOG 3D QA center, but appropriate for prostate brachytherapy.
   b. Publish data exchange protocol specification.
   c. Conduct data transfer testing at the appropriate institutions to verify electronic transfer protocol structure.
   d. Work with the various TIPPB treatment planning system vendors to implement this data exchange specification as has been done with the 3D CRT external beam data exchange.

Task 3. Develop a program for providing centralized quality assurance reviews of treatment planning verification data which would be submitted by participating institutions for

patients receiving TIPPB as part of any future prospective, multi-institutional research trials. (months 1-30)

a. Develop and implement WWW-based graphical review tools to facilitate remote QA review of patient images, organ contours, 2-D dose distribution, and dose-volume histograms (DVHs) of pre-plan results and, from post-implant imaging, review of the dosimetric quality of each implant.
b. Develop and implement electronic notification procedure from 3D QA Center to the participating institution of results of pre-plan analysis and post-implant evaluation.

Task 4. Develop guidelines for the credentialing of institutions enrolled in national prostate brachytherapy trials and establish QA standards for the performance of TIPPB. (months 1-30)

a. Develop a facility questionnaire documenting capability to perform TIPPB. (months 1-3)
b. Design and test a "Dry-Run Test" which each participant must complete to insure that each participant can successfully plan and calculate a simple, geometrically-defined prostate implant. (months 18 and 30)
c. Review the appropriateness of the quality assurance criteria. (months 18 and 30)
d. Publish revised standards for appropriateness of implant quality (months 18 and 30).

Task 5. Develop a dosimetric database to be used in the correlation of implant quality with efficacy of tumor eradication and morbidity of the procedure (months 3-30).

a. Develop the database structure appropriate for TIPPB within the current RTOG dosimetry database system (months 3-6).
b. Implement and test the structure (months 6-24).
c. Periodically evaluate the database for procedural trends and the appropriateness of dosimetric guidelines and quantifiers (months 6-30).

BODY

In this section, we describe the research accomplishments associated with each Task outlined in the approved Statement of Work.

Task 1. Develop and evaluate analytical methods and tools for three-dimensional calculation and dose volume histogram evaluation of prostate brachytherapy (months 1-24).

The RTOG 3DQA center currently uses an in-house developed three-dimensional Radiation Treatment Planning (3DRTP) system that we call "MIR3D" as the QA review station for external beam protocol data submissions. During this funding period, effort has been directed to converting the RTOG 3DQA Center to the use of the commercially available Computerized Medical System, Inc.(CMS) FOCUS 3DRTP system as the TIPPB QA review station. The 3DQA Center was co-developers of this system and thus have access to source code allowing modifications pertinent to QA review functions. The advantage to this conversion is that

FOCUS already includes support for brachytherapy objects and displays, which the MIR3D based QA review station does not. It would have required significantly more development effort to implement those brachytherapy dose calculation, display, and evaluation features on MIR3D as compared to porting the RTOG Data Exchange to FOCUS (see next task) and using the existing brachytherapy features. Thus far the following work has been accomplished:

- FOCUS QA review station isodose display for TIPPB plan review has been tested and is functional. Isodose lines can be displayed on selected CT images and on 3D structures for patient anatomy and target volumes.
- FOCUS QA review station DVH calculation and display for TIPPB plan review has been tested and is functional.

Task 2. Establish a methodology for electronic data exchange of treatment planning verification data between institutions and the 3D QA Center as well as the RTOG Statistical Headquarters (months 1-18).

During this funding period, the major software developmental effort has been directed to implementing the RTOG Data Exchange Specification[1] on the modified CMS FOCUS 3DRTP system that will be used as the TIPPB QA review station. Thus far the following work has been accomplished:

- Teletherapy (CT images, contours, 3D dose matrix, DVHs) READ of RTOG Data Exchange into FOCUS data structures is complete. (Several data submissions have been read into FOCUS submitted from different RTP systems to confirm code is working).
- A draft specification for RTOG Data Exchange that includes brachytherapy seed sources and ultrasound images has been completed. (**See Appendix 1**).
- A TIPPB treatment plan has been entered into our FOCUS 3DRTP QA review station to use in testing of data exchange.
- Work has been completed in implementing a WRITE of RTOG Data Exchange for a TIPPB treatment plan data set per the draft specification.
- A TIPPB plan has been converted to RTOG Data Exchange format. This will allow testing of the READ of RTOG data exchange for brachytherapy structures.
- Modification of the READ of RTOG Data Exchange into FOCUS to include brachytherapy structures has begun.

The 3D QA Center has scheduled a 2-day technical workshop on the clinical implementation of the "***RTOG Data Exchange Specification for Tape/Network Format for Exchange of Treatment Planning Information***[1]." Representatives of several commercial RTP system manufacturers will attend the workshop. The data described by this Specification include CT scans, normal tissue and tumor/target volume contours, beam geometry definitions, volumetric doses, digital film images and dose-volume histograms. This Specification has been expanded (Draft Version 4.00) to include seed implant information including seeds, ultrasound images and

MR images in support of future TIPPB protocols. This workshop will be held on September 10, 1999 from 11:00 AM to 5:00 P.M. and September 11, 1999 from 8:30 AM to 3:00 PM at the Mallinckrodt Institute of Radiology Radiation Oncology Center in St. Louis, MO. The workshop is aimed at the RTP software developer with the goal of this workshop being:

- to present a complete review of the current Draft version of the ***Specification*** including the recent brachytherapy additions;
- to highlight specific issues pertaining to the information required by the ***Specification*** and review the RTOG 3D QA Center requirements beyond the basics of the data exchange;
- to discuss implementation methods and demonstrate a functioning, clinical prototype implementation of the ***Specification*** for writing exchange data files;
- to provide sample source code, written in C, to assist in the implementation of data file generation required by this data exchange.

Please note that it is the 3D QA Center's intention to move toward a complete implementation of the RT-DICOM data objects necessary to support TIPPB trials over the next twelve to twenty-four months. During this time we are optimistic that the treatment planning system vendors will implement complementary capabilities to support such trials and we will be assisting them in appropriate object compliance selections to ensure that the RTOG Data Exchange may ultimately be retired. However, in order to keep the current 3DCRT studies active, as well as to not hinder the newly proposed IMRT and prostate brachytherapy studies, the RTOG Patient Data Exchange will continue to be the medium of exchange until both the 3D QA Center and treatment planning system manufacturers can both provide a RT-DICOM solution.

Task 3. Develop a program for providing centralized quality assurance reviews of treatment planning verification data which would be submitted by participating institutions for patients receiving TIPPB as part of any future prospective, multi-institutional research trials. (months 1-30)

The International Commission on Radiation Units and Measurements (ICRU) Report 50 will serve as the basis for volume definitions. The RTOG 3-D QA Center will provide an independent review of the anatomical definitions of the prostate, bladder, rectum, etc., with feedback to the participating institutions so that these structures will be defined in a uniform manner. The review of TIPPB treatment planning data will include the following: (a) CT scans; (b) GTV, CTV, PTV contours; (c) planning organs at risk (PRV) contours; (d) and dose prescription compliance. The bulk of this data will be submitted in digital form using the RTOG Data Exchange.

Work on WWW-based graphical review tools to facilitate remote QA review from remote locations of patient CT images, organ contours, and dose-volume histograms will begin in the next funding period.

Task 4. Develop guidelines for the credentialing of institutions enrolled in national prostate brachytherapy trials and establish standards for the performance of TIPPB.

Proposed QA guidelines for the conduct of low-dose rate TIPPB for the purpose of performing national, multi institutional cooperative studies have been developed and posted for comment on the 3DQA Center's website (http://rtog3dqa.wustl.edu). A copy of the QA Guidelines is attached at **Appendix 2**. The portion pertaining to credentialing is presented below.

A. General: Brachytherapy, by its nature, is dependent upon the skill of the brachytherapist and the expertise of the support staff. Credentialling therefore needs to address the qualifications and efforts of the implant team as well as the type and quality of available equipment. A credentialling questionnaire is attached as an appendix. The length and detail of the questionnaire is a testament to the variability of the implant procedures performed at different institutions.

B. Equipment

1. Imaging: If ultrasound, fluoroscopy, CT or MRI is used to perform prostate implants, the institution is asked to explain how the imaging capability of the equipment was determined and what regularly scheduled procedures are in place to insure that the equipment continues to meet stated specifications.
2. Treatment Planning: Information pertaining to the system used for pre and post implant planning and evaluation is listed on the credentialling questionnaire. Capabilities and the use of the system in the conduct of the procedure should be detailed, as well as the routine QA tests performed to insure the proper functioning of the treatment planning system (TPS). The method of conducting a second check of the calculations performed by the TPS should be provided as well as the standards ascribed to the comparison between the two systems.
3. Sources: The questionnaire queries the type, form and range of nominal strengths for sources used for prostate implantation. Additionally, the procedures used to insure the receipt and implantation of the proper sources (e.g., assay and handling procedures) should be provided. Assay procedures and regular quality control of the assay equipment will be addressed.

C. Procedures

1. Protocols: Written protocols that describe the implant procedure shall be attached to the questionnaire. These protocols should address, as a minimum, patient selection and flow, procedural scheduling and conduct, source procurement and handling, record keeping and safety procedures.
2. Design Methods: Implant design procedures will be addressed, whether the implants are individually designed prior to the implant or the implants are performed according to a set of rules developed for all cases and modified individually in the operating room. The method of delineating the gross tumor volume (GTV), the clinical target volume (CTV) and the planning target volume (PTV) needs to be provided as well as any regular deviations from the plan (e.g., the insertion of extra sources).

D. Individual Qualifications: The training and experience of the implant team is of paramount importance in the performance of a quality implant and is addressed in the questionnaire.
   1. Radiation Oncologist.
   2. Urologist
   3. Medical Physicist
   4. Dosimetrist
   5. Ultrasonographer
   6. Any other personnel that the brachytherapist feels might materially affect the quality of the implant.

Task 5. Develop a dosimetric database to be used in the correlation of implant quality with efficacy of tumor eradication and morbidity of the procedure (months 3-30).

The RTOG 3D QA Center, together with the RTOG Operations Center and Statistical Center will be responsible for the design, implementation, and support for the prostate implant database. The primary purpose of this database will be to support the quality assurance, data management, and statistical analysis activities for future RTOG and other cooperative group prostate implant protocols. In addition, a secondary purpose is to establish a national resource of readily accessible prostate implant planning data linked to outcomes to be used by clinical investigators for the analysis of secondary long-term clinical outcome studies and by researchers for the development and validation of new tumor control and normal tissue complication models.

In anticipation of a September 1999 Data Exchange workshop, we have begun a review of brachytherapy attributes to be submitted to the QA Center and ultimately represented in the clinical database. Physical data describing radioactive seed isotope, model, strength, and implant locations are represented in version 4.0 of the RTOG Data Exchange format. Since most of the data attributes to be stored in the clinical database will be communicated using the Data Exchange format, the Data Exchange specification will form the starting point for the data modeling effort for these data. Several additional attributes will be needed, however, to interpret submitted data. The database will need to record the number (and locations) of sources at several stages in the planning/implant/verification/QA process: (a) during treatment planning (with respect to pre-plan imaging), (b) at implantation, (c) during verification (with respect to post-implant imaging), and (d) in the QA center (based on received post-implant image data). Modifications of the current CT image data model will be needed to represent image acquisition parameters for MR and US images. Additionally, the time interval between implant and the post-implant CT scan will need to be known (and stored in the database). For trials requiring the submission of more than one volumetric image set, the database will need to represent the relationships between these image sets. A preliminary version of the modified database schema diagram is shown in **Figure 1** below. New entities and relationships used to represent TIPPB data are shaded.

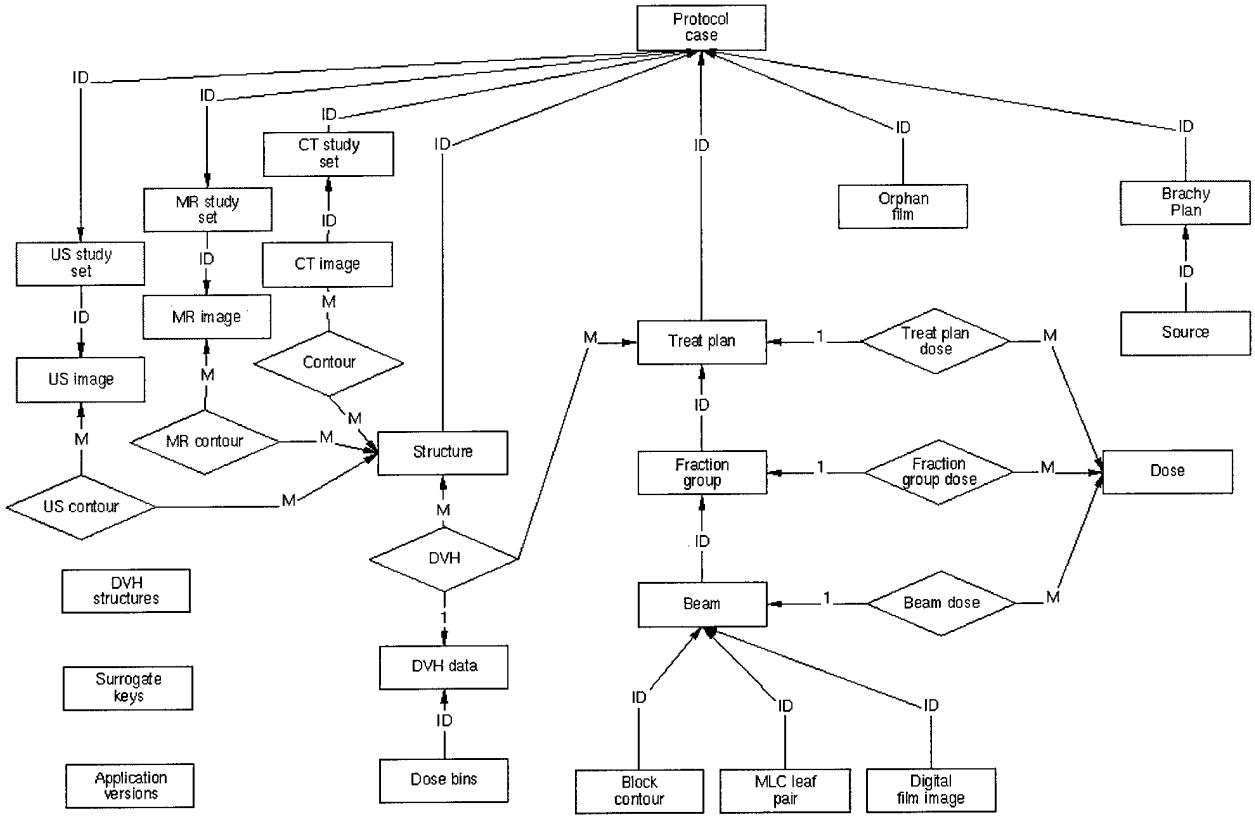

Figure 1: TIPPB Modifications for RTOG 3D Treatment Planning Database Schema

The current database model used by the 3D QA Center utilizes software that involves separate databases for the clinical and administrative data.[2] Thus, in addition to modifications required to store TIPPB treatment planning data, there will also need to be modifications in the administrative database used to track QA reviews of TIPPB cases.

We are currently evaluating several database management system (DBMS) options for implementing QA center databases. The anticipated purchase of new server hardware has raised the question of whether to transfer our existing Sybase SQL Server license to a new hardware platform or to use the opportunity to migrate to an Oracle DBMS. We are weighing concerns of DMBS vendor support for our likely choice of hardware and operating system (Hewlett-Packard), the options for building new applications, and the effort required to migrate existing database tools to a new system.

KEY RESEARCH ACCOMPLISHMENTS

- A draft specification for RTOG Data Exchange that includes brachytherapy seed sources and ultrasound images has been completed. (**See Appendix 1**).
- READ for CT, Contours, and Dose of RTOG Data Exchange into FOCUS data structures has been completed.

- Work has been completed in implementing a WRITE of RTOG Data Exchange for a TIPPB treatment plan data set per the draft specification.
- FOCUS QA review station isodose calculation and display for TIPPB plan review has been tested and is functional. (Isodose can be displayed on CT images and on 3D structures for patient anatomy and target volumes).
- FOCUS QA review station DVH calculation and display for TIPPB plan review has been tested and is functional.
- Proposed QA guidelines for the conduct of low-dose rate TIPPB for the purpose of performing national, multi institutional cooperative studies have been developed. (**See Appendix 2**).
- The RTOG 3D QA center has made plans to hold a Data Exchange workshop at the 3D QA center in St. Louis on September 10-11, 1999. Representatives of several commercial RTP system manufacturers will attend the workshop.

REPORTABLE OUTCOMES

1. 3DQA Center Meeting – October 5, 1998

A meeting of the RTOG/DOD Prostate Cancer Brachytherapy Research Group was held in St. Louis, Missouri on October 5, 1998. 3D QA Center attendees were J. Purdy, B. Harms, W. Bosch and J. Michalski. (Agenda and minutes are attached as **Appendix 3**)

2. RTOG Meeting – January 17, 1999

The 3D QA Center provided an update to the RTOG membership regarding the RTOG/DOD Prostate Cancer Brachytherapy Research Project at the RTOG semi-annual meeting held in Atlanta, Georgia on January 17, 1999. 3D QA Center attendees were J. Purdy and J. Michalski.

2. RTOG Meeting – July 17, 1999

The 3D QA Center provided an update to the RTOG membership regarding the RTOG/DOD Prostate Cancer Brachytherapy Research Project at the RTOG semi-annual meeting held in Philadelphia, PA on July 17, 1999. 3D QA Center attendees were W. Harms and J. Michalski.

CONCLUSIONS

Substantial progress has been made in establishing a methodology for electronic data exchange of TIPPB treatment planning verification data between institutions participating in a future TIPPB protocol and the 3D QA Center. In addition, the RTOG 3-D QA Center has developed a proposed credentialing process and QA guidelines. Work is in progress in modifying a CMS FOCUS 3DRTP system to serve as a 3DQA review station of clinical and dosimetric data for

patients entered on RTOG and other cooperative group TIPPB protocols. Work will begin in the next funding period on the development of remote review tools and a national database for the TIPPB treatment planning data that can be linked with clinical outcome data.

REFERENCES

1. Harms, W.B., Bosch, W.R. and Purdy, J.A.: An Interim Digital Data Exchange Standard for Multi-Institutional 3D Conformal Radiation Therapy Trials. Leavitt, D.D. and Starkschall, G (eds). XII ICCR, Salt Lake City, Utah, May 27-30, 1997, Medical Physics Publishing, Madison, WI, pp. 465-468, 1997.

2. Bosch, W.R., Lakanen, T.L., Kahn, M.G., Harms, W.B. and Purdy, J.A.: An Image/Clinical Database for Multi-Institutional Clinical Trials in 3D Conformal Radiation Therapy. Leavitt, D.D. and Starkschall, G (eds). XII ICCR, Salt Lake City, Utah, May 27-30, 1997, Medical Physics Publishing, Madison, WI, pp. 455-457, 1997.

APPENDICES

Appendix 1: Draft specification for RTOG Data Exchange that includes brachytherapy seed sources and ultrasound images.

Appendix 2: Proposed QA guidelines for the conduct of national, multi institutional cooperative studies of low-dose rate TIPPB.

Appendix 3: Agenda and minutes for RTOG/DOD Prostate Cancer Brachytherapy Research Group Meeting held in St. Louis, Missouri on October 5, 1998.

Appendix 1

Specifications for Tape/Network Format for Exchange of Treatment Planning Information

RTOG 3D QA Center

William Harms
RTOG 3D Quality Assurance Center
Washington University
510 South Kingshighway Blvd.
St. Louis, MO 63110

Version 4.00 **(DRAFT)**
22 June 1999

Please send suggestions and comments to:

Bill Harms

Based on **AAPM Report #10** and as used and modified by the **NCI Particle Intercomparison Contract,** the **NCI High Energy Photon External Beam Treatment Planning Contract,** the **NCI Electron External Beam Treatment Planning Contract,** and the **RTOG 3D QA Center.**

CONTENTS

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0. PREFACE

This Tape/Network Format Specification, while initially based on AAPM Report #10, has been significantly altered to allow more information to be included in the data transfer. It was originally modified by the NCI Particle Intercomparison contract, then used in that form by the NCI High Energy Photon External Beam contract. The document was modified further for the NCI Electron External Beam contract. The modification in this version reflect further trimming of unused image types with the intent to add more image types that directly impact on exchange of treatment planning and treatment verification.

A significant modification was made with version 3.00 as it included several heretofore unsupported data image types. These new image types include beam geometries, digital film images, and dose-volume histograms. Additionally, several changes were made to dose distributions to remove ambiguities involving the submission of other than absolute dose.

With Version 3.10, an apparently ambiguous keyword was removed and more clarifying comments and examples were added. An additional keyword was added for beam geometry to identify the algorithm used for calculating doses from the beam. All of these additional keyword additions, or deletions, are optional in nature to maintain compatibility with Version 3.00. To simplify network exchange of these data files, the requirement for "buffered" data blocks is removed as an option (to be agreed upon by sending and receiving site). As many institutions are originally writing their files in this format and then post processing them to "block" them, this should come as a welcome change. This "unbuffered" submission is only available for electronic exchange of the data and the use of buffers will still be required for any tape media data exchanges.

Version 3.20 added an additional keyword for digital film images "Collimator Angle" (primarily DRR's without portal marking in the image) and one for beam geometry "Head In/Out". These were to clear up ambiguities and oversights in the previous version. DRR's are computed by two primary geometric methods, one removes the collimator angle from the transformation matrix used for computing the DRR and the other always has the edges of the image parallel to the collimators (the collimator angle is left in the transformation matrix). The "Collimator Angle" keyword identifies the method being used and is optional if the DRR edges are parallel to the unrotated collimator. The

"Head In/Out" was added to resolve potential ambiguity in the couch angle wherein a 180 degree offset was added to the couch angle to signify a foot in treatment. If that patient is being treated with their feet to the gantry (prior to any couch rotation), this keyword must be used, otherwise, head in is assumed.

Changes were made in the document for Version 3.21 which mostly amounted to additional explanation of keywords and data inclusion. There were several keywords for Beam Geometry, Digital Films and Dose-Volume Histograms which were moved from the *Required Keywords* to *Optional Keywords*. This was primarily to simplify the directories by removing requirement on any data which was not necessary to interpreting the data provided in the file set.

As more institutions begin to participate in studies requiring the use of this data exchange specification, it is inevitable that further refinement and ambiguity resolution will have to be done. This is a living document and will be subject to many revisions over the next year or two until it is replaced with more robust and universal communication mechanisms such as DICOM 3.0.

Version 4.00 was created to provide for ultrasound guided permanent prostate seed implants. Additional items were added in support of Peregrine and other projects. Those which were added which are not supported by the 3D QA Center are identified as such in the text.

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1. REVISION HISTORY

Version	Date	Description
1.0	4/22/82	Preliminary draft. (Michael Goitein)
1.1	8/28/82	Substantially modified. All images in ACSII except CT scans
1.2	10/21/83	Intermediate update - never distributed.
2.1	12/27/83	Working version. Document clarified and reorganized. New requirement that CT images be contiguous on tape in order of increasing z-coordinate Explicit description of how null characters are to be handled. (nulls not included in byte counts).
2.2	4/08/85	Revisions made in conjunction with Robert F. Curley: Add dose examples Add text describing in words the data files for structures and doses. Require "....." must not contain CR/LF Require all CT scans to be square. Add a number of clarifying comments.
2.3	09/22/89	Remove annotations and code examples for ECWG report (Harms)
2.4	07/08/92	Remove additional information on annotations, cleaned up the grammar, added variances relating to the amount of data on a tape (multiple patients, buffer size, and tape density), added new "image" types of MRI, Beam Geometry, and digital film images (i.e. DRR, on-line images). (Harms)
2.5	06/29/93	Fixed errors in document pertaining to keywords "Maximum # of scans" to "Maximum # scans" and "Scan type" to "Scanner type" (Harms)
2.51	07/09/93	Clean up language and add "Writer" as a Directory Header entry (as it was inadvertantly left out from the original format)

3.00	1/10/94	Added Beam Geometry, Digital Film, DVH's and fractionation information. Included moving appendices into appropriate chapters and modified dose distributions to allow for fractionation information and to clarify dose units. (Prostate Working Group, Bill Harms, Jonathan Jacky, Jeff Lewis and James Balter).
3.10	6/10/94	Added more explanation and cleaned up some partial omissions. Allowed unblocked data (for network transmission) if receiving site is agreeable and removed "INTERCOMPARISON STANDARD #" as an ambiguous keyword. Removed AAPM Report 10 as the standard to judge discrepancies in the exchange format.
3.20	12/28/94	Added "Head In/Out" keyword to beam geometry and "Collimator Angle" keyword to digital film images for DRR's.
3.21	3/8/95	Added clarifying discussion to many keywords and moved unnecessary keywords from Required, to Optional.
3.22	4/17/97	Corrected error in MLC example.
3.30	7/25/97	Optional extensions added to Beam Geometry and Dose for support of Peregrine communications and more succinct and explicit treatment plan information exchange. Some additional clarification text was incorporated based on comments by George Starckschall. The primary additions to Beam Geometry are explicit compensating filter descriptions, a Machine ID keyword (in addition to energy and modality), and Beam Weight and Weight Units to allow for machine settings to be specified. The optional additions to Dose allows for binary dose files (two's complement integer with a scale factor) to reduce the size of dose image files. Following are links to the modified text for ease of locating. • ASCII restrictions • Date Format for Y2K • Coordinate System Clarification • Asymmetric Jaw Clarification • Compensating Filters • Additional Beam Geometry (Optional) Keywords • Digital Film Modification (Text) • Digital Film Modification (Keywords) • Dose Modification for Binary Data (Text) • Binary Dose Sample Description • Additional Dose Keywords (Optional) for Binary Data (Keywords) • DVH Data Format Clarification
4.00 Draft	03/22/1999	Changes made for Version 4.0 of this Exchange Specification were motivated by the need to add prostate seed brachytherapy treatment planning to the information supported by this exchange. In order to make use of the appropriate imaging modalities which are used for permanent prostate seed implants, MRI and ultrasound (US) were added to the CT Scans chapter and an additional file type was defined for Seed Plan specification. One previously documented feature has been removed. While the Specification

"officially" supported multiple patient data sets in a single file set, no commercial or University systems being used for patients enrolled in multi-institutional trials made use of this feature, therefore, to simplify the implementation of reading and writing software, this feature has been removed. This allows the Case keyword to be used as desired by the writing facility. A suggestion would be to use the actual patient registration number as the case number, but in order to maintain backward compatibility with writing software, this is not going to become a requirement at this time.

One additional change was to incorporate beam aperture definitions through the use of a transmission table in addition to closed block and portal contours. This addition was made to facilitate the exchange of this information with the Peregrine system and is not currently used, or supported by the RTOG 3D QA Center for protocol patient data submissions.

Following are links to the modified text for ease of locating. Also, note that all added text is in this same color purple text to aid the reader. Incorrect compensating filter examples were also corrected.

- Case number modification
- Patient Coordinate system clarification for CT, MRI, and Ultrasound image sets
- MRI and Ultrasound image files
- Warning about MLC Specification
- Transmission Map Information (in lieu of block or MLC coordinate specification)
- Compensating filter example data correction
- Seed Geometry

2. INTRODUCTION

The format proposed follows the recommendations of the AAPM for digital image transfer, published as AAPM report no. 10, "A Standard Format for Digital Image Exchange" (obtainable from: AAPM, One Physics Ellipse, College Park, MD 20740). The description in this document assumes the reader's familiarity with AAPM Report #10. The tape format described in this document is intended to comply with all aspects of AAPM Report #10. Some aspects of that report are reiterated here as a help to the reader. However, in the event of a real or apparent discrepancy, AAPM Report #10 shall give way to this document. This document extends the scope of AAPM report #10 by including data structures other than CT scans or comparable images.

Seven types of files (termed images in the AAPM standard) are supported (in addition to the Directory): Comments; CT scans; Structures (target volumes, external contours, normal critical structures, etc.); Beam Geometry's; Dose distributions; Digital Film Images and Dose-Volume Histograms. No more than one case can be transmitted on one tape (or network file data set). The data shall be placed on tape in the following order, case by case.

Comments	case 1
Scans (CT, MRI, US)	case 1
Structures	case 1
Orphan Digital Film Images	case 1
Beam Geometry's	case 1 (plan 1)
Digital Film Images	case 1 (plan 1)
Doses	case 1 (plan 1)
Dose-Volume Hist.	case 1 (plan 1)
Beam Geometry's	case 1 (plan 2)
Digital Film Images	case 1 (plan 2)
Doses	case 1 (plan 2)
Dose-Volume Hist.	case 1 (plan 2)
.....	.....
Beam Geometry's	case 1 (plan n)
Digital Film Images	case 1 (plan n)
Doses	case 1 (plan n)
Dose-Volume Hist.	case 1 (plan n)
etc.	

Not all data is required in this order. For instance, if beam geometry's and digital film images are not submitted with the corresponding doses and dose-volume histograms, the non-existent data will just be left out of the data to be transmitted. An example of such an order would be:

Scans	case 1
Structures	case 1
Doses	case 1 (plan 1)
Dose-Volume Hist.	case 1 (plan 1)
Doses	case 1 (plan 2)
Dose-Volume Hist.	case 1 (plan 2)
.....	.....
Doses	case 1 (plan n)
Dose-Volume Hist.	case 1 (plan n)
etc.	

Examples of a directory header and some (non-binary) images are included in the following chapters.

There are two distinct coordinate systems used by this Specification. One is for patient data which is defined in Chapter 6. The other is for the beam aperture specification which is oriented in a "beam's-eye view" manner in which aperture coordinates are 2D coordinates with a constant third coordinate relative to distance from beam source and is defined in Chapter 8.

3. DISTRIBUTION MEDIA CONVENTIONS

3.1 TAPE EXCHANGE

A 9-track tape with a density of 1600 bpi shall be the default medium used for data exchange. However, if the site to receive the tape agrees to higher density, and/or a different type of physical tape, it shall be allowed. Tapes shall be UNLABELED to facilitate intercommunication between different manufacturer's computers. Multi-volume tapes should not be used unless necessary to transmit a single case. For tapes which can have their densities changed, the tape must be clearly labeled and the used density agreed to by the receiving institution.

All data on the tape shall be written in fixed length buffers. The default buffer size is 2048 bytes, but if the receiving site agrees to a different size buffer, it is allowed and should be clearly marked on the tape. As many buffers are written as are required to transmit the data, unused bytes (such as the unused remaining bytes of the last buffer of an image) shall be filled with NULL characters. No text strings should be broken across buffer boundaries. If an entire string will not fit into the current buffer, the end of the buffer should be NULL'ed out and the string put into the next buffer.

Single end-of-file marks separate the directory file from the first "image" file and succeeding image files from one another. Two end-of-file marks in succession terminate the tape. On media other than 9-track tape, these separation requirements may not be valid and adjustments may need to be made.

3.2 NETWORK EXCHANGE

If both the sending and receiving site have network access to one another, this data may be sent as individual files across the network. The means of such transfer are left for the sending and receiving institutions to work out among themselves. Recent experience has shown that anonymous ftp, in binary mode, is a practical method of such data transfer where the files' names have a numeric identifier in their names so that the order is obvious for processing (the author's preference is "aapm0000", "aapm0001", etc.). However, anonymous ftp might present patient record confidentiality problems. This could require the submitting institution(s) to have distinct login accounts on the receiving machine(s) which segregate them from other institutions data submissions and shield the data they submit from others.

For network exchange of data, if the receiving site agrees, the data may be sent in files of a single buffer the size of the data file. The fixed length buffer requirement may be disregarded in this case. However, for media exchange of data, in the interest of preventing any possible hardware/software incompatibility, fixed buffers are still REQUIRED. This is a change for Version 3.10.

3.3 DATA STORAGE

Two types of data can be stored on tape: BINARY data, for CT scans and digital film images; and ASCII character strings (terminated with <CR/LF>) for everything else (including the directory file). The two types of data may **NOT** be mixed within any given file.

3.3.1 BINARY Data

For each binary datum which occupies 2 bytes of the buffer, in compliance with the AAPM standard, the most significant byte is required to be first. Thus VMS, and similar byte order, machines will need to byte-swap both when writing and when reading a tape, for instance. For the unsigned byte data, the

order is obvious.

3.3.2 ASCII Data

ASCII data may appear in one of two contexts: In the directory header where the data is always in the form of keyword/value pairs (see below); and in images (such as structure definitions or dose distributions) - where the format depends on the data type, but is generally largely a sequence of numeric fields (i.e. ASCII strings defining real or integer numbers as appropriate). In either context the following rules apply.

Each entry of ASCII text may be from 1 to 80 bytes in length (excluding null bytes which are ignored) and **must** be terminated by a carriage-return/line-feed (CR/LF) sequence (not included in the 80 byte limit). Embedded spaces, tabs and null characters should not be included within numeric fields (but may precede or follow them) and elsewhere (as in keywords) they are to be ignored. Blank lines (CR/LF/CR/LF) are to be ignored in the parsing of these files. To permit comments in numeric fields (in order to make a printed file more interpretable), any text enclosed in double quotation marks (") is to be ignored. Text between quotation marks may not include a CR/LF string.

When specifying numeric data, a comma/space (comma followed by a space) sequence is an acceptable field delimiter as well as the CR/LF sequence. *ADD1: Note, however, that no text line may end with a comma/space/CR/LF sequence as the comma/space implies further meaningful text in the line.* No text string may bridge multiple buffers, if buffered exchange is selected or required. While the specification technically allows it, it generally presents implementation problems and shall not be supported.

3.3.3 NULL Characters

Unused elements of the last buffer of a binary image (if any) are ignored. They may be filled with zeros.

Null characters may occur anywhere within ASCII Text (except in the middle of a numeric field) and are to be ignored. Null characters are not counted in any per line byte count limit. Generally, it is expected that null characters will be used to pad out at least the final buffer of an image, and should be used to pad out the final elements of intermediate buffers to avoid having text cross buffer boundaries. Only binary data may cross buffer boundaries.

---

4. DIRECTORY

The first file is a directory file, written entirely in ASCII characters. The directory consists entirely of Keyword/Value pairs - as described in the AAPM standard specification and in this document. At present no files or "images" other than the directory contain keyword/value sequences. Keywords and values are case and space insensitive. For instance:

```
Somewhat longer keyword :=
```

is equivalent to:

```
SOMEWHAT      LONGER          KeyworRd :=.
```

The first entries in the directory pertain to the entire tape and constitute the "directory header". Keywords used in the directory header are given in the following section. The directory header is followed by sequences of keywords which relate to individual images. By convention the first such keyword shall be "Image #", and all keywords relating to an image should follow that "Image #" specification and should precede the next "Image #" occurrence.

Note that "Image #" is a misnomer introduced by the AAPM format for tape exchange. It really just identified the position of the file on the tape. However, it does reference the sequence number of the associated file for network transferred data files. The first file is the directory (perhaps best thought of as file number 0), and subsequent files are termed "images" and assigned consecutive numbers starting from 1. In the present case, these "images" may in fact be any one of: Comments, CT scans, Structures, Beam Geometry's, Digital Film Images, Dose Distributions and DVH's.

Spaces, tabs and null characters are to be ignored in keywords. Alphabetic characters may be in upper or lower case and, in interpreting strings of characters as keywords (program implementation), all lower case characters may be replaced by their upper (or lower) case equivalents. In order to remove a potential source of confusion, the character strings "number" and "#" in keywords are to be everywhere considered interchangeable and **MUST** have numeric values.

In conformity with the AAPM standard, directory entries are made in the format:

```
Keyword :=  value
```

In this context only one "value" can follow the "=". Thus a mixed expression such as "size : = 1.5 cm" is illegal. There is to be no character (null, space, or otherwise) between the ":" and the "=".

In order to make tape listings somewhat more readable, it is permissible (indeed encouraged) to include tabs to make successive entries line up, as:

```
Keyword                  :=    STRUCTURES
Somewhat longer keyword  :=    18
Next keyword             :=    10.65
```

The AAPM *tape* format virtually mandates a two-pass approach - that is, two passes have to be made through the data to be transferred: the first in order to build up and write out the entire directory; the second in order to write out the underlying data to tape. This may be avoided if the files are built on disk first and the physical writing of the tape subsequent to the completion of all data files and the directory being written to disk. Network transfer will involve building the files on disk with the directory file being written to disk last (even though it has a smaller file number, i.e. 0).

4.1 Keywords for the Directory Header

Required Keywords

```
Tape standard # :=    4.00  (version # of this standard from title page)
Institution     :=    Name of submitting institution
Date created    :=    Date tape written in AAPM format (dd, mm, yyyy)
Writer          :=    Name of person responsible for writing tape
```

These entries **must** be the first entries in the directory.

Optional Keywords

```
Intercomparison standard # :=   version # of this standard from title
                                page (4.00) this keyword is maintained
                                only for compatibility and its' use is
                                not recommended
```

Format of data in the image:

No image is associated with the directory header.

4.2 Sample Entries in the Directory Header

```
Tape standard # :=    4.00
Institution     :=    MIR
Date created    :=    22, 03, 1999
Writer          :=    Bill Harms
```

The date format used for all dates specified in a directory for a data exchange file set must be in the format DD, MM, YY[YY], where DD is the day of the month (one or two digits are allowed), MM is the month of the year (one or two digits are allowed and 1-January, 2-February, etc.), and YY is the last two digits of the year with an implied 1900 added to it. *Four digits may be used for the year for Y2K compliance (and **must be used after 12/31/1999**).*

Note that a date may be legal in format, but due to the time of any given month in which the date is generated, it may be incorrect. For instance, if a file set is generated on the 9th of February 1995, the date string should be `9, 2, 95`. However, `2, 9, 1995` is a legitimately formatted date, but is incorrect. This should be carefully reviewed during implementation as it is a frequent mistake.

There are four keywords which are common to all image files (regardless of the image file content). These keywords must be used for all image files and must be in the order specified for the proper implementation of the data exchange format.

Required Keywords

```
Image #       :=    actual image (file) number
Image type    :=    COMMENT, CT SCAN, MRI, ULTRASOUND, STRUCTURE,
                    BEAM GEOMETRY, DIGITAL FILM, DOSE,
                    SEED GEOMETRY, or DOSE VOLUME HISTOGRAM
Case #        :=    1 for first case(optionally protocol case #)
Patient name  :=    patient identifier
```

The Image # is the ordinal number of the data file being referenced. In the case of tape being used as the transport medium, this number is the order in which the files are found on the tape in which the first file is the directory file and is considered file number zero (0). Therefore the first data file would be 1, the second, 2, etc. In the case of a network medium of exchange, these number must be explicitly represented in the file names attached to the individual files. Again, the directory file is file zero (0).

The Image type is used to identify the data contained in the associated image file. With the exception of CT SCAN, MRI, ULTRASOUND, DIGITAL FILM and binary dose files (optional) all data files are in ASCII format.

The Case # identifies the ordinal value of a patient in an exchange file set. Since multiple patient data sets are eliminated from this specification, this number may have any integral value and one suggestion would be to make it represent the case number assigned by the cooperative group for the protocol the patient is enrolled in.

The Patient name is not required to be the patient's real name. However, it should have the same value for all image files for the same patient in the exchange file set. For RTOG 3D QA Center purposes, it should be the patient's name or some other identifier which the submitting institution can use to identify the data set in question should the 3D QA Center have questions about the case..

```
Image #      :=    1
Image type   :=    COMMENT, CT SCAN, STRUCTURE, BEAM GEOMETRY,
                   DIGITAL FILM, DOSE, or DOSE VOLUME HISTOGRAM
Case #       :=    1
Patient name :=    John Q. Public
```

---

5. COMMENT

This feature provides the capability of transmitting substantial textual material such as a clinical case history. The format of the data is as a sequence of ASCII text strings, each of no more than 80 characters, of arbitrary length. Although the comment text can be entered in any way desired, the most likely mechanism would be to provide a utility to read a file created with the computer's text editor and copy it into the comment "image" after adding the appropriate <cr/lf> line terminators and buffering. An example in 5.3 illustrates this.

5.1 Keywords for Comments Used in Directory

Required Keywords

```
Image #              :=    actual image (file) number (see 4.4)
Image type           :=    COMMENT
Case #               :=    1 for first case, 2 for second case, etc.
Patient name         :=    patient identifier
```

Optional Keywords

```
Writer               :=    person responsible for data
Date written         :=    date file written (DD, MM, YYYY)
Unit #               :=    data identifier (submitting site)
File of origin       :=    Name of original file.
Comment description  :=    brief title to characterize comments
```

Format of data in the image:

ASCII text.

5.2 Sample Entries in the Directory

```
Image #              :=    1
Image type           :=    COMMENT
```

```
Case #              :=    1
Patient name        :=    FALSENAME
Unit #              :=    01-23-456
Comment description :=    Example of a comment file
```

5.3 Sample Image File

This is an example of comment text. It can be used to transmit information about the case being transmitted, or anything else.

Many such "images" can be put on one tape, and more than one can apply to any one case. The directory entry "comment description" is a useful way of indicating what is in this file so that the recipient of the tape can decide on the urgency with which to approach the task of looking at the comment.

---

6. CT SCAN, MRI AND ULTRASOUND IMAGES

CT scans, MR images and ultrasound images (hereafter referred to as Patient Images or PI) are two dimensional arrays of 8 or 16 bit numbers. In the case of the 16 bit numbers, they are to be packed most significant byte first in accordance with the AAPM format. Patient Images (PI) are required to have square pixels (size of grid 1 units is the same as the grid 2 units). With the publication of Version 4.00, non-squarePI are now supported. The PI pixel numbers are required to be POSITIVE in the range 0 to 32767 for 16 bit pixels and 0 to 255 for 8 bit pixels - which means that some offset must be added to the Hounsfield (or other) numbers natural to the scanner to ensure that this constraint is complied with. In the case of 8 bit data, the data type is *unsigned byte* which requires that if the 8 bit data is handled as positive and negative values on the submitting system, an offset must be provided to ensure proper order of the pixel values..

To define the CT scale fully the user is required to provide two constants, CT-AIR and CT-WATER which are, respectively, the values of the transmitted data which correspond to air and water. If, for example, the user added 1024 to Hounsfield numbers of a perfectly calibrated scanner the constants would have the values CT-AIR = 0 and CT-WATER = 1024. The CT offset should be large enough that no negative binary values are written in the CT data and no CT value is greater than 32767.

Many scanners have an imperfect CT scale, so that air and water do not have their nominal values. This can be corrected by supplying the correct values (rather than the nominal values) for CT-AIR and CT-WATER. Non-linear behavior is possible. If the user has corrected for this the keyword/value "CT *scale := Linearized"* must be provided. If the CT numbers have been transformed to water-equivalent densities the keywords/value "CT *Scale := Water-equivalent"* must be provided. If the CT numbers transmitted should be distrusted above the certain value, that value should be specified with the "Distrust above" keyword.

6.1 Coordinate System and Scan Offsets

The pixel data are to be ordered so that, if a scan is considered to be viewed from the patient's feet, the first pixel would correspond to the upper left hand corner of the scan, subsequent pixels would correspond to the data in the first row going from left to right followed by the pixels of the second and subsequent rows, ending at the lower right hand corner.

A right-handed cartesian coordinate system - referred to as the PATIENT COORDINATE SYSTEM - is superimposed on the scans. *ADD2: The z axis is positive pointing out of the paper, which always points toward the patient's feet. It should be noted that this is DIFFERENT from the IEC patient coordinate system.*

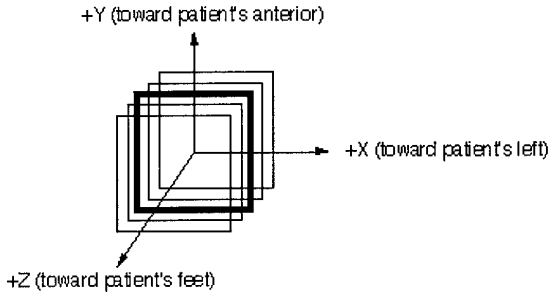


Figure 6.1

Figure 6.1 illustrates the coordinate system. The axes depicted in Figure 6.1 represent a patient who is scanned head first in a supine position. The coordinate system is more accurately described as a "hybrid" coordinate system where X and Y are independent upon the patient orientation on an external beam treatment unit couch and the Z coordinate is based on patient scan order. While the Figure 6.1 anatomical labels correspond to the identified axes when scanned head first, supine, the X and Y coordinate axes are actually tied to a treatment couch with +X to the right of the gantry when viewed from the couch and +Y is up toward the ceiling (assumes couch position orthogonal to plane of gantry rotation). The +Z coordinate is always toward the patient's feet independent of their scanning or treatment orientation which may require inverting this coordinate value depending upon the order maintained by the RTP system. With regard to coordinate system for brachytherapy data exchange, the anatomical labels and the corresponding axes identified in Figure 6.1 must be used.

Generally the origin of the patient coordinate system is at the dead center of the CT/MRI/US image (element 160.5, 160.5 of a 320x320 array, for instance where 1 refers to the first pixel in the image). However, offsets of the images are permitted as indicated in the following figure. Offsets are positive when the displacement is in the indicated directions as in Figure 6.2:

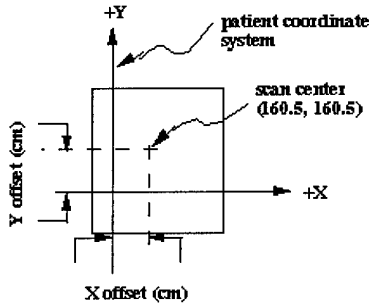


Figure 6.2

Scans must be provided in contiguous order on tape (or in the file set), in order of monotonically increasing value of the z coordinate. However, a sequence of scans need not be uniformly spaced along the axis normal to the plane of the scans (z axis).

In terms of this coordinate system, CT/MRI/US data are to be stored within the data array in the following manner: The upper left hand corner pixel (least x, greatest y) is first, followed by pixels in the first row (i.e. the x dimension is incremented first), followed by subsequent rows of lesser y value until the bottom right (greatest x, least y) pixel terminates the array. With the exception of some keyword changes, the MRI/US image format is almost identical to that of the CT scan images both in terms of the actual pixel data as well as in the directory structure entries.

6.2 Keywords for Images Used in CT Scan Directory

Required Keywords

Image #	:=	actual image (file) number (see 4.4)
Image type	:=	CT SCAN identifies as CT scan
Case #	:=	1 for first case, 2 for second case, etc.
Patient name	:=	patient identifier
Scan type	:=	TRANSVERSE
CT offset	:=	see text
Grid 1 units	:=	pixel width (cm.)
Grid 2 units	:=	pixel height (cm.) Must be same as Grid 1 units
Number representation	:=	TWO'S COMPLEMENT INTEGER
Bytes per pixel	:=	must equal 2
Number of dimensions	:=	must equal 2
Size of dimension 1	:=	number of rows
Size of dimension 2	:=	number of columns
z value	:=	couch position (cm, + to feet)
x offset	:=	usually 0.0 (cm) [signed x distance from coordinate system's x origin to the geometric center of the CT scan pixel image]
y offset	:=	usually 0.0 (cm) [signed y distance from coordinate system's y origin to the geometric center of the CT scan pixel image]
CT-air	:=	256 at MGH
CT-water	:=	1256 at MGH

Optional Keywords

Unit #	:=	Unit number or ID
Site of Interest	:=	"pancreas", etc. - see below
Scan description	:=	"contrast study", etc.
Scanner type	:=	GE9800, SIEMENS DRH, etc.
Head in/out	:=	IN, OUT
Position in scan	:=	NOSE UP, NOSE DOWN, LEFT SIDE DOWN, RIGHT SIDE DOWN
Patient attitude	:=	RECUMBENT, SEATED, STANDING
Tape of origin	:=	helps you retrieve your original data
Study number of origin	:=	helps you retrieve your original data
Scan ID	:=	original scan identifier
Scan #	:=	scan # in this sequence
Scan date	:=	use AAPM format (DD, MM, YYYY)
Scan file name	:=	original file name
Slice thickness	:=	in cm.
CT scale	:=	LINEARIZED, WATER-EQUIVALENT
Distrust above	:=	maximum credible CT value

The pixel sizes (Grid 1 or 2 units) are positive for transverse oriented images. All coordinates and linear dimensions are expressed in centimeters.

Format of data in the image file:

Binary data in two's complement integer 0 to 32767.

6.3 Sample Entries in the Directory

Only the first two scans of this data set are shown.

```
Image #                 :=    1
Image Type              :=    CT SCAN
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
CT Offset               :=    1024
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    TWO'S COMPLEMENT INTEGER
Bytes per Pixel         :=    2
Number of Dimensions    :=    2
Size of Dimension 1     :=    512
Size of Dimension 2     :=    512
Z value                 :=    7.5000
X Offset                :=    0.0000
Y Offset                :=    0.0000
CT-air                  :=    0
CT-WATER                :=    1024
SCAN #                  :=    1
Slice Thickness         :=    0.5000

Image #                 :=    2
Image Type              :=    CT SCAN
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
CT Offset               :=    1024
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    TWO'S COMPLEMENT INTEGER
Bytes per Pixel         :=    2
Number of Dimensions    :=    2
Size of Dimension 1     :=    512
Size of Dimension 2     :=    512
Z value                 :=    8.0000
X Offset                :=    0.0000
Y Offset                :=    0.0000
CT-air                  :=    0
CT-WATER                :=    1024
SCAN #                  :=    2
Slice Thickness         :=    0.5000
```

and so on for the remainder of the scans.

6.4 Sample Image of Data for CT Scan

Data are in 16-bit, 2's complement, integer representation but are required to be within the 0 to 32767 range. Data is in raster order with the first pixel being the upper left of the image (i.e. the most negative x coordinate pixel and the most positive y coordinate pixel), the next pixel being just to the right of the first pixel until that raster line is complete, then all remaining raster lines until the last

pixel (lower right).

6.5 Keywords for Images Used in MRI/US Scan Directory

Required Keywords

```
Image #                 :=    actual image (file) number (see 4.4)
Image type              :=    MRI or ULTRASOUND
Case #                  :=    1 or Registered case number (numeric only)
Patient name            :=    patient identifier
Scan type               :=    TRANSVERSE
Pixel offset            :=    value added to each pixel to ensure >= 0 for all p:
Grid 1 units            :=    pixel width (cm.)
Grid 2 units            :=    pixel height (cm.) Must be same as Grid 1
                              units
Number representation   :=    TWO'S COMPLEMENT INTEGER or UNSIGNED BYTE
Bytes per pixel         :=    2 for two's complement or 1 for unsigned byte
Number of dimensions    :=    must equal 2
Size of dimension 1     :=    number of rows
Size of dimension 2     :=    number of columns
z value                 :=    couch position (cm, + to feet)
x offset                :=    usually 0.0 (cm) [signed x distance from
                              coordinate system's x origin to the
                              geometric center of the CT scan pixel image]
y offset                :=    usually 0.0 (cm) [signed y distance from
                              coordinate system's y origin to the
                              geometric center of the CT scan pixel image]
```

Optional Keywords

```
Scan date               :=    use AAPM format (DD, MM, YYYY)
```

The pixel sizes (Grid 1 or 2 units) are positive for transverse oriented images. All coordinates and linear dimensions are expressed in centimeters.

Format of data in the image file:

Binary data in two's complement integer 0 to 32767 or byte 0 to 255.

6.6 Sample Entries in the MRI/US Directory

Only the first two scans of this data set are shown.

```
Image #                 :=    1
Image Type              :=    MRI
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
Pixel Offset            :=    127
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Number of Dimensions    :=    2
Size of Dimension 1     :=    256
Size of Dimension 2     :=    256
Z value                 :=    5.5000
X Offset                :=    0.0000
```

```
Y Offset                :=    0.0000
Scan Date               :=    22, 06, 1999

Image #                 :=    2
Image Type              :=    ULTRASOUND
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
Pixel Offset            :=    0
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Number of Dimensions    :=    2
Size of Dimension 1     :=    256
Size of Dimension 2     :=    256
Z value                 :=    -3.0000
X Offset                :=    0.0000
Y Offset                :=    0.0000
```

and so on for the remainder of the scans.

6.7 Sample Image of Data for MRI/US Scan

Data are either in 16-bit, 2's complement, integer representation but are required to be within the 0 to 32767 range or in 8-bit unsigned byte within 0 to 255. Data is in raster order with the first pixel being the upper left of the image (i.e. the most negative x coordinate pixel and the most positive y coordinate pixel), the next pixel being just to the right of the first pixel until that raster line is complete, then all remaining raster lines until the last pixel (lower right).

---

7. STRUCTURES

Structures are connected sequences of three-dimensional coordinates which define volumes of interest such as the target volume. A "structure" has a variety of attributes, including a "name", "edition number", "color", free text "description", etc.

The organization of the points is that they are grouped together in planes which coincide with planes on which CT scans are centered. A given structure does not have to be defined in all planes in which scans exist, but the planes in which it is defined are contiguous. That is, no planes are "skipped".

Within a given plane, a structure will consist of one or more "segments" (usually just one). Each segment is a sequence of at least four (4) points which are connected and the last and first points must be the same (that is, the segment is "closed"). These points define a generally irregular curve which lies on the surface of the volume being defined. All segments need not have the same number of points. Segments in contiguous scans are assumed to be connected in some way so as to form the surface of the volume. The reason for permitting more than one segment per plane is so that Y-shaped or O-shaped structures may be defined.

The current definition of structures is tied closely to a scan sequence, paralleling what is currently done in most programs. More general definitions, requiring a more general data structure, may be

needed in future. The keyword/value sequence "Structure format:=Scan-based" shall be included to permit subsequent expansion.

The following figure suggests how the components of a structure are arranged. The coordinates are in centimeters and are relative to the PATIENT COORDINATE SYSTEM defined above (Figure 7.1).

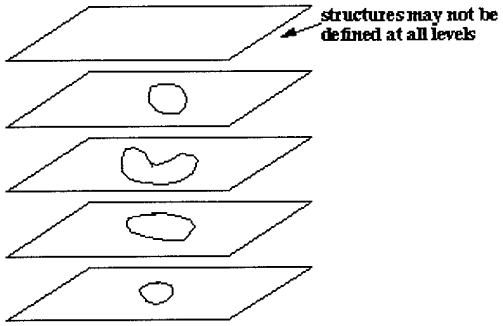


Figure 7.1

The data storage in a structure's image is "defined" through the example in Section 7.3. The data are placed in the buffer in the following order:

```
Number of levels (total # of scans)
  Scan number (=1 for first scan, etc.)
    Number of segments in this level (scan)
      number of points in first segment
      triplets of (x, y, z) coordinates, one per point, last=first
      number of points in second segment
      triplets of (x, y ,z) coordinates, one per point, last=first
```

Scan number (=2 for second scan,) Number of segments in this level (scan) number of points in first segment triplets of (x, y, z) coordinates, one per point, last=first number of points in second segment triplets of (x, y ,z) coordinates, one per point, last=first

Comments may be embedded in the data file if enclosed in quotes as documented in 3.2.1.

Scans must be contiguous on tape. This supports the data structure of structures which presumes that sequential contours are associated with sequential (contiguous) scans ordered monotonically with increasing value of the associated z coordinate. **All scans must be referenced (in order) even if the structure does not exist in a particular slice.** In this case the only data in the file will be the Scan # and the Number of Segments (0). See Section 7.3 for an example of this.

7.1 Keywords for Images Used in Directory

Required Keywords

```
Image #                    :=   actual image (file) number (see 4.4)
Image type                 :=   STRUCTURE
Case #                     :=   1 for first patient,
                                2 for second patient, etc.
Patient name               :=   patient identifier
Structure name             :=   structure identifier (liver, heart,
                                etc.)
Number Representation      :=   CHARACTER
```

```
Structure format            :=   SCAN-BASED
Number of scans             :=   same as # CT scans in the exchange
                                 file set
Maximum # scans             :=   100 or system limit (may be set to
                                 Number of scans value)
Maximum points per segment  :=   200 or system limit
Maximum segments per scan   :=   2 or system limit
```

Optional Keywords

```
Unit #                      :=   unit number or ID
Writer                      :=   person responsible for this data
Date written                :=   AAPM format date (DD, MM, YYYY)
Structure edition           :=   1 or higher
Structure color             :=   RED, GREEN, BLUE, YELLOW, MAGENTA,
                                 CYAN OR WHITE
Structure description       :=   Free form text
Study # of origin           :=   for submitting institution's
                                 identification
Orientation of structure    :=   TRANSVERSE
```

Format of data in the image:

ASCII Text

7.2 Sample Entries in the Directory

```
Image #                     :=   56
Image Type                  :=   STRUCTURE
Case #                      :=   1
Patient Name                :=   BREAST1B
Structure Name              :=   EXTERNAL
Number Representation       :=   CHARACTER
Structure Format            :=   SCAN-BASED
Number of Scans             :=   55
Maximum # scans             :=   128
Maximum Points per Segment  :=   200
Maximum Segments per Scan   :=   4

Image #                     :=   57
Image Type                  :=   STRUCTURE
Case #                      :=   1
Patient Name                :=   BREAST1B
Structure Name              :=   TARGET
Number Representation       :=   CHARACTER
Structure Format            :=   SCAN-BASED
Number of Scans             :=   55
Maximum # scans             :=   128
Maximum Points per Segment  :=   200
Maximum Segments per Scan   :=   4
```

7.3 Sample Image Data for Structure

```
"NUMBER OF LEVELS"    55
"SCAN # "    1
"# OF SEGMENTS "    0
"SCAN # "    2
"# OF SEGMENTS "    0
"SCAN # "    3
"# OF SEGMENTS "    0
```

```
"SCAN # "    4
"# OF SEGMENTS "    0
(8 structure scan numbers omitted here)
"SCAN # "  13
"# OF SEGMENTS "    0
"SCAN # "  14
"# OF SEGMENTS "    0
"SCAN # "  15
"# OF SEGMENTS "    0
"SCAN # "  16
"# OF SEGMENTS "    0
"SCAN # "  17
"# OF SEGMENTS "    0
"SCAN # "  18
"# OF SEGMENTS "    1
"# OF POINTS    "  15
  -6.440,    5.850,   -3.500
  -6.230,    5.890,   -3.500
 (11 coordinate triplets omitted here)
  -6.660,    5.620,   -3.500
  -6.440,    5.850,   -3.500
"SCAN # "  19
"# OF SEGMENTS "    1
"# OF POINTS    "  32
  -6.260,    7.190,   -3.000
  -6.350,    7.240,   -3.000
  -6.350,    7.240,   -3.000
(28 coordinate triplets omitted here)
   -6.260,    7.190,   -3.000
"SCAN # "  20
"# OF SEGMENTS "    1
"# OF POINTS    "  27
  -7.590,    7.580,   -2.500
  -7.300,    7.690,   -2.500
```

etc.

---

8. BEAM GEOMETRY

Beam geometry's are to be be transferred as one data file per beam with the data file containing the information defining the beam aperture information. Some of the formalism herein is borrowed from the Foundation Library Specification and Virtual Machine Platform (VMP) Specification document from the Radiotherapy Treatment Planning Tools Collaborative Working Group (Tech. Report 91-1, Ira Kalet, Ph.D., Radiation Oncology Department RC-08, University of Washington, Seattle, WA 98125, USA).

There are several pieces of information required to be able to build a "treatment plan" using beam geometries. The first is the particular beam definition itself, including the prescribed dose per treatment of this field as well as the number of treatments delivered. Second is the identification of other beams that are treated in the same fraction(s) with this beam so that fractionation information may be obtained. Additionally, the grouping of all beams which are treated (or may be treated) is also provided so that a composite of all treatments may be reconstructed and the fractionation data with it.

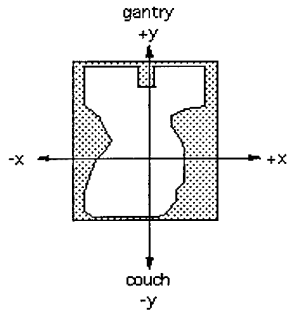
The origin of the beam coordinate system (for the aperture definition) is defined with the treatment machine's collimator rotated to the neutral position (e.g. new Varian machines allow collimator angles from 90 to 270 degrees with 180 being the "neutral" position) and the gantry angle set such that the

beam is pointed at the floor (down). The +y axis is toward the machine gantry when viewing along the beam's central axis with the gantry toward the top of your head. The +x axis is to your right when using the same view. All coordinates for apertures are in this unrotated coordinate system. All collimator, gantry and couch angles are defined to be zero for the gantry pointed down, the couch longitudinal axis orthogonal to the plane of gantry rotation and the collimator's +y axis is along the couch's longitudinal axis and is pointed toward the gantry. See Figure 8.1.

Angles are positive in the counter-clockwise (CCW) direction. CCW is defined from the above view for collimator and couch rotation and as viewed when looking into the gantry from the couch for the gantry rotation. The assumed patient orientation is with head to gantry. If the patient is being treated with foot to gantry, the keyword HEAD I/OUT must be used with a key value of OUT. The HEAD IN/OUT keyword may also be standardly used for head in as well but is required for head out treatments. For example, a right lateral beam for a patient oriented with head to gantry will have a gantry angle of 90 degrees, while the gantry angle would be 270 degrees for a right lateral beam with the patient's feet toward the gantry.

Beam shapes may be specified by MLC settings, contours for custom portal blocks and, for use with Peregrine and similar systems, by transmission maps. For a simple block, or MLC field, the map points inside the open regions of the beam would have a transmission value of 1.000. The map points under the MLC leafs or block will have transmission values appropriate with recommendations and/or requirements of receiving system. The 3D QA Center does not support the use of transmission maps for block specification.

Note that dynamic, conformal therapy and intensity modulation are not explicitly accounted for here and are left for future expansion.



View is from beam source along the central axis with the beam pointing at the floor (gantry angle = 0 and collimator angle = 0)

Figure 8.1

8.1 Data Contained in the Image File

The data in the image file is as follows:

- Coordinate of machine isocenter (or nominal source reference point distance for machines without a rotational center) in centimeters in the patient coordinate system.
- Collimator setting(s) for the x jaws (e.g. 25.0 for SYMMETRIC, or 11.0, 14.0 for ASYMMETRIC -- negative values are for a jaw that crosses and blocks the central axis)
- Collimator setting(s) for the y jaws (e.g. 25.0 for SYMMETRIC, or 11.0, 14.0 for ASYMMETRIC -- negative values are for a jaw that crosses and blocks the central axis)

ADD3: For asymmetric collimator specifications the jaw which normally resides to the left (negative X in beam coordinates) or to the bottom (negative Y in beam coordinates) is specified first followed by the opposing jaw position. Again, note that a negative coordinate for an asymmetric jaw value implies that it has crossed the central ray. For instance, an asymmetric collimators setting of 11.0, 14.0 for X and -2.0, 8.0 for Y results in a 25.0 cm wide by 6.0 cm long rectangle which is centered at +1.5 cm in X and +5.0 cm in Y.

For APERTURE TYPE := COLLIMATOR

- No additional data is included (yes this does seem a bit wasteful of space but should be an anomaly for conformal therapy). However, an empty file of minimal length must be provided to maintain consistency and order in the format. In the case of conformal therapy (for which this format was extended) this empty file is improbable.

For APERTURE TYPE := BLOCK

- # of block contours (the following are repeated for each contour)
- Block type (0 = aperture definition, 1=block definition) for block. Only one aperture is allowed per beam while multple blocks are allowed.
- Block fractional transmission under block (must be less than 1.00)
- # of block coordinate pairs (must close the contour) for block
- Coordinate pairs for block contour

For APERTURE TYPE := MLC_X or MLC_Y

- # of leaf pairs
- Center coordinate for each leaf pair in increasing coordinate (y values for MLC_X, x values for MLC_Y)
- Thickness of each leaf pair in cm.
- Extension coordinates for each leaf pair where a negative value denotes extension across the central axis (minimum x or y, maximum x or y leaf position).
- NOTE that most currently available commercial MLC collimators are MLC_X only. Generally MLC_Y or MLC_XY is not appropriate for use

For APERTURE TYPE := MLC_XY

- # of leaf pairs in x
- Center coordinate for each leaf pair in increasing coordinate (y values)
- Thickness of each x leaf pair in cm.
- Extension coordinates for each x leaf pair where a negative value (x) denotes extension across the central axis.
- # of leaf pairs in y
- Center coordinate for each leaf pair in increasing coordinate (x values)
- Thickness of each x leaf pair in cm.
- Extension coordinates for each y leaf pair where a negative value (y) denotes extension across the central axis (minimum x or y, maximum x or y leaf position).

For APERTURE TYPE := TRANSMISSION_MAP

- # of X transmission values (I), # of Y transmission values (J)
- size of square transmission element (cm) (transmission maps are required to use square map elements, but matrix may be rectangular)
- X1, Y1 (starting coordinate in cm of the center of the upper-left map element, -X, +Y in beam coordinates)
- # of transmission value, block thickness pairs (N)
- transmission value #1, block thickness #1 (cm)
- transmission value #2, block thickness #2 (cm)
- .....
- .....
- .....
- transmission value #N, block thickness #N (cm)
- ROW #1 transmission values
- ROW #2 transmission values
- .....
- .....
- .....
- ROW #J transmission values

If blocks are used, only one *aperture definition* is allowed although there is no strict limit on block definitions. This is to prevent system dependent ambiguity which would arise in the case of multiple apertures. The assumption this specification makes is that once a ray from a beam is blocked, it stays blocked. In the case of an aperture, all points outside of the contour are implicitly blocked, therefore they remain blocked.

Transmission Map Description

The transmission map specification involves three primary bits of data. The first is the matrix specification for the map for a rectangular matrix of square transmission elements. This specification includes the size of the square elements, the number of elements in each row and column and the coordinate of the center of the elements (not a corner). Another is a transmission value for the rectangular matrix made up of square elements where the transmission numbers represent the appropriate transmission value for the block material used according to the requirements of the receiving system. Points not under any block material will have a transmission value of 1.00 with lesser values for points under attenuators (MLC or block). Lastly, a map of block material thickness versus transmission value to define the physical characteristics of the portal shaping device. This implies that there are only as many distinct transmission values as are defined in the list of thicknesses and transmission values.

The order of the data in the file (for the transmission map) is identical to that used for compensating filters. The transmission values are specified in raster order from the most negative X and most positive Y coordinate (in beam coordinates) to the most positive X coordinate and most positive Y coordinate for the first row, followed by each subsequent row (see Figure 8.2).

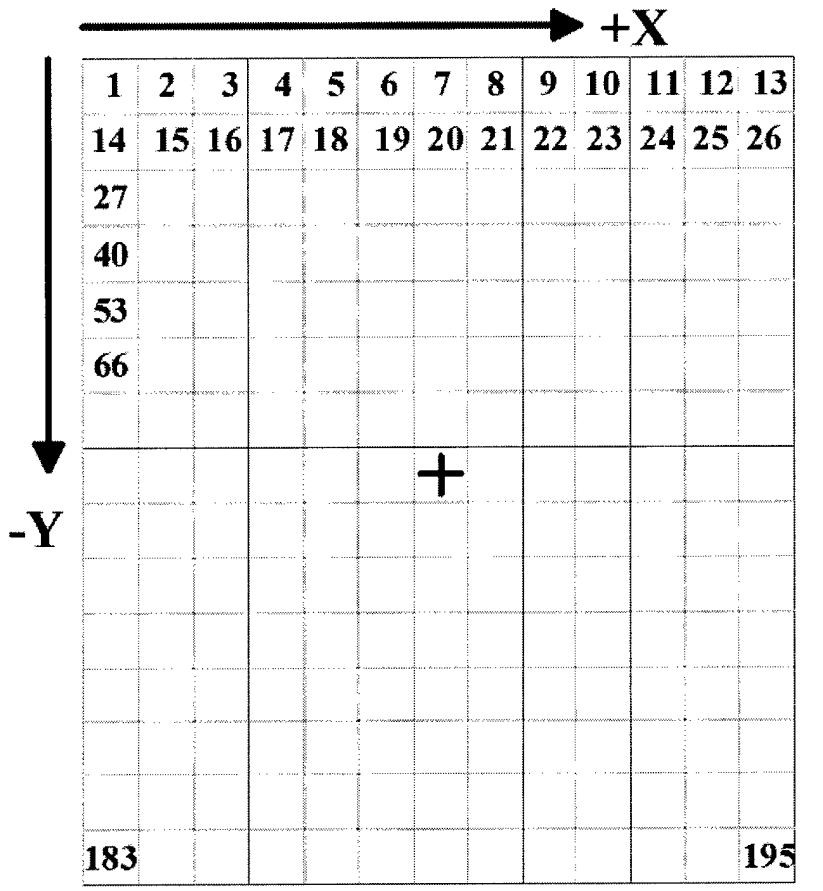


Figure 8.2

An example of the data in a transmission map beam data file is as follows. Note that the isocenter and collimator information is first in the file, followed by the transmission map followed by any compensator information.

```
"# of X Elements" 101, "# of Y elements" 85
"Size of square matrix element (cm)" 0.15
"Center of X1, Y1 (cm)" -7.5, 6.3
"# of transmission value thickness pairs" 2
"Pair #1" 1.0000, 0.0
"Pair #2" 0.0325, 8.1
"NX" 8, "NY" 6
"ROW #1"0.0325, 0.0325, 0.0325, 0.0325, 0.0325, 0.0325, 0.0325, (etc)
"ROW #2"0.0325, 0.0325, 0.0325, 1.0000, 1.0000, 1.0000, 1.0000, (etc)
Compensating filter information follows.
```

ADD4:**Compensating Filters**

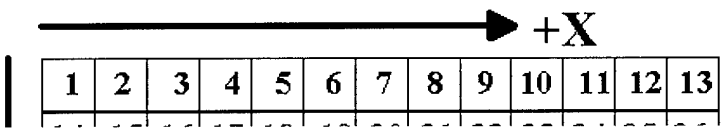
Compensating filters may be specified in an abbreviated or extended form. The abbreviated form is identical to that used for Version 3.22 of this Specification. That uses only a "flag" to indicate that a compensating filter was used through use of the COMPENSATOR keyword and the appropriate keyvalue (NONE, 1D-X, 1D-Y, 2D, or 3D).

The extended form allows for either construction or attenuation information to be provided using the new keyword COMPENSATOR FORMAT. The key values available for use with this keyword are: THICKNESS, ATTENUATION, TISSUE, or NONE. Using the NONE keyvalue is identical to the results obtrained through using only the COMPENSATOR keyword with the appropriate flag and not including the COMPENSATOR FORMAT keyword (identical to the Version 3.22 capability). The other key values (THICKNESS, ATTENUATION and TISSUE) indicate that a matrix of compensating filter construction is being supplied in the beam data file. This matrix specification and data is in the data file following all other beam geometry information (isocenter, collimators, blocks and/or MLC specifications). In the case of ATTENUATION, the matrix values are fractional transmission (i.e. 0.25 indicates that 25% of the impinging radiation is transmitted). There is no explicit or implict statement about whether the attenuation values are narrow or broad beam. The matrix values in the data file for THICKNESS indicate the thickness of the construction material in cm. It is assumed that the receiving system has predefined information necessary to appropriately use this information for dose calculation (e.g. construction material). For TISSUE specified compensators, the matrix values correspond to the thickness of unit density tissue which must be accounted for. This generic specification may allow for appropriate interpretation by construction systems or devices.

2D or 3D Compensator Construction Specification

As the only difference between 2D and 3D compensators is the inclusion, or exclusion, of heterogeneity corrections for their design, they are specified in identical fashion as a two-dimensional grid defined at the NOMINAL ISOCENTER DISTANCE specified for the beam in which the delta-x between all columns in the matrix is uniform as is the delta-y between rows, but where the delta-x and delta-y are not required to be equal to each other (but, probably will be). The compensator matrix data is specified in raster order such that the starting coordinate specified is to the upper left (least X and greatest Y matrix element) of the grid (similar to the order of dose matrix values in a transverse plane). Because it is assumed that each matrix element occupies space, the starting coordinate specified (and the coordinates for other elements computed) are in the center of a region of attenuation with width delta-X and length delta-Y. Specifying the center of the matrix element causes the X1, Y1 coordinates to be offset by one-half the delta of the axis from the corner of the physical compensator (toward positive X and negative Y). The data is formatted as follows:

1. NX, NY (integer number of columns and rows)
2. delta-X, delta-Y (floating point interval between columns [greater than 0.0], floating point interval between rows [less than 0.0])
3. X1, Y1 (starting coordinate in cm of the center of the upper-left matrix element, -X, +Y in beam coordinates)
4. beam attenuation coefficient (1/cm) for THICKNESS specifications, or 1.00 for ATTENUATION and TISSUE specifications
5. ROW #1 attenuation or thickness values
6. ROW #2 attenuation or thickness values
7. ...
8. ...
9. ROW #NY attenuation or thickness values



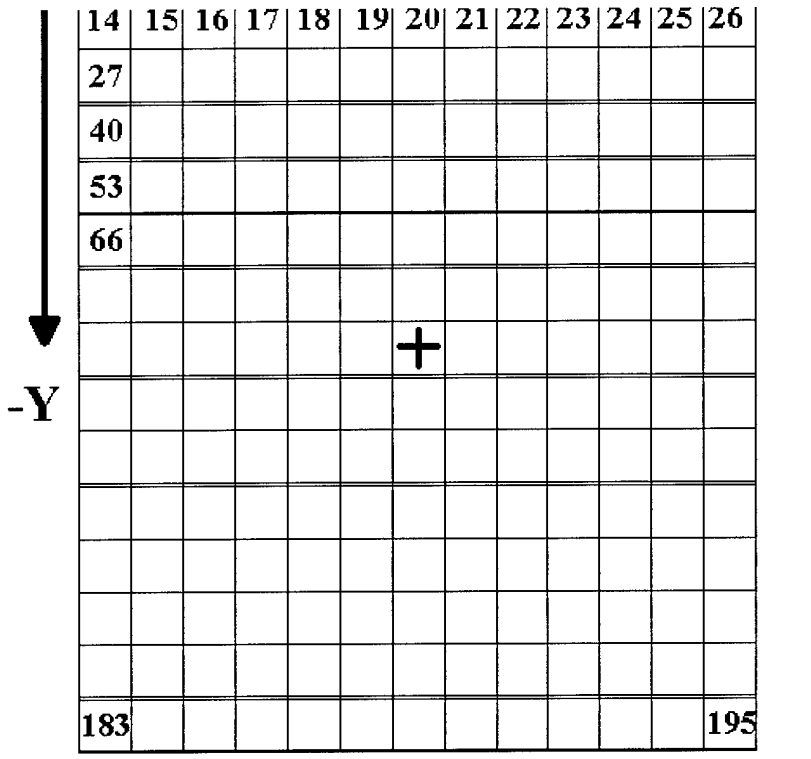


Figure 8.3

Figure 8.3 demonstrates the order of compensating filter data in the data file using the numbers in the individual compensator cells. Note that this is in raster order with a positive delta-X and a negative delta-Y. This figure shows the central ray of the beam through the center of a grid element, however, this is not required and the grid may align in any fashion with the major axes of the beam.

A simple (non-realistic) example of a 2D or 3D compensator construction text file follows. This sample is for a VERY SIMPLE compensator for a SMALL field for a beam with a NOMINAL ISOCENTER DISTANCE of 100.0 cm and for which the compensator matrix elements project to 1.5 cm wide at this distance. The collimator settings are symmetric along both axes and result in a field size of 10.0 cm x 7.0 cm at this same distance. The COMPENSATOR FORMAT is ATTENUATION. For compensating filter specification in thicknesses, it is assumed that the receiving system has some predefined understanding of the material used for construction. This compensator information follows the isocenter, collimator and blocking specification information.

```
"NX" 8, "NY" 6
"delta-X (cm)" 1.50, "delta-Y (cm)" 1.50
"X1, Y1" -7.25, 3.75
"Attenuation value per cm" 1.00
"ROW #1"0.872, 0.880, 0.820, 0.820, 0.850, 0.850, 0.900, 0.900
"ROW #2"0.900, 0.900, 0.820, 0.850, 0.850, 0.850, 0.900, 0.900
"ROW #3"0.900, 0.900, 0.850, 0.850, 0.850, 0.950, 0.950, 0.872
"ROW #4"0.900, 0.900, 0.850, 0.800, 0.900, 1.000, 0.950, 0.872
"ROW #5"0.872, 0.900, 0.850, 0.800, 0.850, 0.950, 0.900, 0.900
"ROW #6"0.872, 0.880, 0.820, 0.820, 0.850, 0.850, 0.900, 0.900
```

The 1D compensator (or custom step-wedge) is more simply specified as it contains only a single

array corresponding to the axis across the steps (X or Y). Because the steps of these types of systems are not necessarily regularly spaced, the compensator is specified much like a cumulative histogram plot with each step being specified by a starting beam coordinate (at the NOMINAL ISOCENTER DISTANCE) and a thickness or attenuation value which is considered constant to the coordinate of the next step specified. Note that the type (ATTENUATION, TISSUE or THICKNESS) are handled in the same manner as that for 2D and 3D compensators. The slabs must be specified order of increasing coordinate (X or Y, as appropriate).

1. N (integer number of compensator steps)
2. beam attenuation coefficient (1/cm) for THICKNESS specifications, or 1.00 for ATTENUATION and TISSUE specifications
3. SLAB #1 starting coordinate, attenuation or thickness values
4. SLAB #2 starting coordinate, attenuation or thickness values
5. ...
6. ...
7. SLAB #N starting coordinate, 0

A simple example of a 1D compensator data file entry for a 1D-X compensator specified by THICKNESS follows:

```
"NX" 8
"Attenuation value per cm" 0.967
"SLAB #1 X-coordinate"-10.00, 0.000
"SLAB #2 X-coordinate" -9.00, 0.600
"SLAB #3 X-coordinate" -7.00, 1.200
"SLAB #4 X-coordinate" -3.00, 1.800
"SLAB #5 X-coordinate"  0.00, 2.400
"SLAB #6 X-coordinate"  1.00, 3.000
"SLAB #7 X-coordinate"  3.00, 3.600
"SLAB #8 X-coordinate"  6.00, 4.200
"SLAB #9 X-coordinate"  8.00, 4.800
"SLAB #10 X-coordinate" 10.00, 4.200
"SLAB #11 X-coordinate" 11.00, 0.000
```

There is no extrapolation or extension of compensator information beyond the coordinate values covered by the explicit compensator specification. Specifying a compensator smaller that the open field dimensions on the skin will have indeterminate results.

Following are the keywords for the Beam Geometry definition in the directory file:

8.2 Keywords for Images Used in Directory

Required Keywords

```
Image #                 :=   actual image (file) number (see 4.4)
Image Type              :=   BEAM GEOMETRY
Case #                  :=   1 for first case, 2 for second case
                             in file set, etc.
Patient Name            :=   patient identifier
Beam #                  :=   Beam number in plan of origin (to
                             index with dose files later)
Beam Modality           :=   X-RAY, ELECTRON, PROTON, NEUTRON, OTHER
Beam Energy(MeV)        :=   Beam energy in MeV
Beam Description        :=   Text Description of beam (i.e. LPO,
                             AP Boost, etc.)
Rx Dose Per Tx (Gy)     :=   ICRU Reference point dose per treatment
```

Rx Dose Per Tx (Gy)	:=	Tx's reference point dose per treatment (generally, isocenter dose)
Number of Tx	:=	Number of treatments using this field
Fraction Group ID	:=	ID to group beams of common fraction
Beam Type	:=	STATIC, ARC
Collimator Type	:=	SYMMETRIC, ASYMMETRIC, ASYMMETRIC_X, ASYMMETRIC_Y
Aperture Type	:=	BLOCK, MLC_X, MLC_Y, MLC_XY, COLLIMATOR, or TRANSMISSION MAP
Collimator Angle	:=	Collimator angle in degrees
Gantry Angle	:=	Gantry angle in degrees (also start angle for an arc beam)
Couch Angle	:=	Couch angle in degrees
Nominal Isocenter Dist	:=	Rotational source-isocenter distance in cm or nominal treatment distance (i.e. 80.0 cm for Co-60)
Number Representation	:=	CHARACTER

Optional Keywords

Plan ID of Origin	:=	Plan ID of beam origin for grouping beams and doses
Aperture Description	:=	Description of beam aperture
Aperture ID	:=	Identifier of Aperture for beam
Wedge Angle	:=	Wedge angle in degrees (required if wedges are used for this beam)
Wedge Rotation Angle	:=	0, 90, 180, 270 (required if wedges are used for this beam) where: 0 - toe of wedge points toward +y beam axis 90 - toe of wedge points toward +x beam axis 180 - toe of wedge points toward -y beam axis 270 - toe of wedge points toward -x beam axis
Arc Angle	:=	Arc angle in degrees (Req'd of ARC Beam Type) it's sign should reflect the stopping gantry angle.
Machine ID	:=	text string uniquely identifying machine parameter set used for dose calculation
Beam Weight	:=	numeric value specifying beam weight used (or to be used) for dose calculation with definition of this value driven by the WEIGHT UNITS keyword
Weight Units	:=	MU, RELATIVE or PERCENT MU is actual monitor unit (or time) setting used for each treatment RELATIVE is the fractional amount of total beam on time for this beam versus the total beam on time PERCENT is the percentage amount of total beam on time for this beam versus the total beam on time **BEAM WEIGHT and BEAM UNITS are both required if either one of them is used**
Compensator	:=	NONE, 1D-X, 1D-Y, 2D, 3D where: 1D is a customized step wedge along specified beam axis 2D is a topographic correcting compensator (an Ellis type for instance) 3D corrects for topography and heterogeneity
Compensator Format	:=	THICKNESS, TRANSMISSION, TISSUE or NONE where: THICKNESS indicates the compensator is specified in ray thicknesses in cm TRANSMISSION indicates the compensator is specified in ray transmission values TISSUE indicates the compensator is

```
                                  specified in ray thicknesses in cm of tissue
                                NONE indicates the compensator's
                                  construction is not specified (default if this
                                  keyword not used for a compensator)
Head In/Out             :=    IN, OUT where:
                              IN specifies this beam treated with
                                the patient's head toward the gantry
                                (prior to any couch rotation), and
                              OUT specifies this beam treated with
                                the patient's head away from the gantry
                                (prior to any couch rotation).
                              NOTE: Orientation is assumed to be
                              head in unless otherwise specified.
                              This keyword is required for a foot
                              in treatment.
```

Format of data in the image file:

ASCII TEXT

8.3 Sample Entries in the Directory

```
Image #                 :=    25
Image Type              :=    BEAM GEOMETRY
Case #                  :=    1
Patient Name            :=    Joe Smith
Beam #                  :=    1
Beam Modality           :=    X-RAY
Beam Energy(MeV)        :=    18
Beam Description        :=    AP Port
Rx Dose Per Tx (Gy)     :=    1.00
Number of Tx            :=    25
Beam Type               :=    STATIC
Plan ID of Origin       :=    final
Collimator Type         :=    ASYMMETRIC_X
Aperture Type           :=    BLOCK
Aperture Description    :=    AP Portal Large Field
Collimator Angle        :=    0
Gantry Angle            :=    0
Couch Angle             :=    0
Nominal Isocenter Dist  :=    100.0
Aperture ID             :=    AP Port Block
Compensator             :=    1D-Y
Number Representation   :=    CHARACTER
Fraction Group ID:      :=    1
Head In/Out:            :=    IN
```

8.4 Sample Image of Beam Geometry Data

```
"Isocenter coordinate" 1.0, -2.5, 15.2
"Collimator Setting x" 11.0, -2.5
"Collimator Setting y" 15.0
"# of block contours" 2
"Block #1 type contour encloses open portal" 0
"Transmission under block" 0.03125
"# of block coordinate pairs" 6
-10.5,   7.0,   -3.0,   7.0,  -3.0,  -7.2,  -5.0,  -4.3,  -9.5,  -6.5
-10.5,   7.0
"Block #2 type contour encloses spinal shield" 1
```

```
"Transmission under block" 0.03125
"# of block coordinate pairs" 5
-7.5,   7.5,   -5.5,   7.5,  -5.5,  -7.5,  -7.5,  -7.5,  -7.5,   7.5
"Compensating filter data as shown above"
```

Here is a short example of a multi-leaf data file (MLC_X) with asymmetric collimators in x (ASYMMETRIC_X). All coordinates are defined at the *Nominal Isocenter Distance*. Note that words in quotes are to be ignored by the processing program as documented in Section 3.1.2.

```
"Isocenter coordinate" 1.0, -2.5, 15.2
"Collimator Setting x" 11.0, -2.5
"Collimator Setting y" 15.0
"Number of Leaf Pairs" 26
"Leaf center y positions"    -12.5, -11.5, -10.5,  -9.5,  -8.5,  -7.5
 -6.5,  -5.5,  -4.5,  -3.5,  -2.5,  -1.5,  -0.5,   0.5,   1.5,   2.5
  3.5,   4.5,   5.5,   6.5,   7.5,   8.5,   9.5,  10.5,  11.5,  12.5
"Leaf pair thickness"  1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0
  1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0
  1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0
"Leaf extensions for Y1"   -8.81,  8.81
"Leaf extensions for Y2"   -8.81,  8.81
"Leaf extensions for Y3"   -8.81,  8.81
"Leaf extensions for Y4"   -8.81,  8.81
"Leaf extensions for Y5"   -8.81,  8.81
"Leaf extensions for Y6"    6.86,  6.95
"Leaf extensions for Y7"    7.93,  7.96
"Leaf extensions for Y8"    8.31,  8.26
"Leaf extensions for Y9"    8.31,  8.25
"Leaf extensions for Y10"   8.30,  8.25
"Leaf extensions for Y11"   8.30,  8.25
"Leaf extensions for Y12"   8.30,  8.25
"Leaf extensions for Y13"   8.29,  8.24
"Leaf extensions for Y14"   8.29,  8.23
"Leaf extensions for Y15"   7.91,  7.79
"Leaf extensions for Y16"   7.50,  7.36
"Leaf extensions for Y17"   6.50,  6.92
"Leaf extensions for Y18"   6.68,  6.49
"Leaf extensions for Y19"   6.27,  6.05
"Leaf extensions for Y20"   5.86,  5.62
"Leaf extensions for Y21"   5.45,  5.18
"Leaf extensions for Y22"   5.04,  4.74
"Leaf extensions for Y23"   4.63,  4.31
"Leaf extensions for Y24"  -8.81,  8.81
"Leaf extensions for Y25"  -8.81,  8.81
"Leaf extensions for Y26"  -8.81,  8.81
"Compensating filter data as shown above"
```

9. DIGITAL FILM IMAGES

This image type supports the exchange of digitized simulation films, digitized portal films, on-line portal images, and computed images (i.e. DRR's). The basic information to be included is the pixel data itself and identifiers so that one image may be distinquished from another when multiple images of the same field are used. The pixels themselves are to be transferred in raster order where the first pixel is the upper left pixel of the image with the most rapid change in position with changing pixel is to the right of the image. The last pixel in the image is the lower right.

The film coordinate system is identical to that used for the Beam Geometry images with respect to the

The film coordinate system is identical to that used for the Beam Geometry images with respect to the x and y offsets and axes. The DRR digital film image is assumed to be aligned with the unrotated collimator. For example, if the pixel image were to be displayed on a monitor with the collimators superimposed, the collimator edges would be rotated (relative to the edges of the display) if the collimator angle is other than 0 degrees (or a multiple of 90 degrees). If DRR's are aligned with the collimator edges, regardless of the collimator rotation, the COLLIMATOR ANGLE keyword must be used and its' value must be the collimator angle for the associated beam. This angle will be assumed to be zero (implying that the film does not rotate with the collimator) unless this keyword and appropriate value are used.

There are parameters which may be included in the directory to describe a digital film which are designed to define the alignment of the image in the associated radiation beam. While these parameters are necessary for any digital film image (particularly for DRR's), which does not have either a fiducial grid or a port outline on it from which such alignment may be derived, they are not generally required for SIMULATOR or PORT image files. Generally, since this alignment information is available for DRR images, such alignment data is required. The affected keywords are: Grid 1 Units, Grid 2 Units, Source Image Distance, X offset, Y offset and Collimator Angle. Where zero (0) is implicit in the image data (for instance, DRR's are generally constructed such that the central ray is in the geometric center of the pixel image) these keywords are not required. For DRR images Grid 1 Units, Grid 2 Units, Source Image Distance are required keywords, while the use of X offset, Y offset and Collimator Angle depend on the context of the image generation as described with the keyword. None of these keywords is required for SIMULATOR or PORT images.

The pixel data is transferred in a fashion similar to the CT pixels, in that they may be 16 bit unsigned integer values whose range is restricted to 0 to 32767 or may be in a range of 0 to 255 for unsigned byte data. The number of bits per pixel acutally containing data may be specified in order to facilitate the use of local packing and display software.

Since it is possible to have multiple images of the same port in one day, the combination of date and film number uniquely identify a film. Generally, the film number will be 1, but multiple images of the same port in a day are supported through this method.

ADD5: In order to facilitate the exchange of digital film images without having an attached beam in a fraction group (for instance a urethrogram film or perhaps orthogonal isocenter verification films without corresponding beams in the treated fraction groups), the BEAM # and BEAM DESCRIPTION keywords have been made optional. The condition to their optional nature is that if they are not used, the FILM DESCRIPTION keyword must be used and vice versa.

9.1 Keywords for Images Used in Directory

Required Keywords

```
Image #              :=   actual image (file) number (see 4.4)
Image Type           :=   DIGITAL FILM
Case #               :=   1 for first case, 2 for second case in
                          file set
Patient Name         :=   Patient Identifier

Film Number          :=   Number of film on particular date (i.e.
                          1, 2, etc.)
Film Date            :=   Date digital image acquired (DD, MM, YYYY)
```

Film Type	:=	SIMULATOR, DRR, PORT
Number of Dimensions	:=	2 (always)
Size of Dimension 1	:=	number of rows
Size of Dimension 2	:=	number of cols
Number Representation	:=	TWO'S COMPLEMENT INTEGER (for 2 bytes per pixel) or UNSIGNED BYTE (for 1 byte per pixel)
Bytes per Pixel	:=	1 or 2 (must index with Number Representation)

Optional Keywords

Beam #	:=	Beam number in plan of origin (to tie image with) Required if film belongs to a beam in a submitted fraction group.
Beam Description	:=	Text description of beam generating image Required if film belongs to a beam in a submitted fraction group
Film Description	:=	Text Description of film Required if BEAM # and BEAM DESCRIPTION keywords not used and must be the same identical string for all appropriate films (i.e. AP ISOCENTER, RT LAT ISOCENTER, etc.)
Grid 1 Units	:=	pixel width (cm) (required for DRR's)
Grid 2 Units	:=	pixel length (cm)(required for DRR's)
Source Image Distance	:=	equivalent to TFD (cm)(required for DRR's)
X Offset	:=	X offset from geometric center of image to central ray of the beam (required for DRR's where central ray is not in geometric center of pixel image)
Y Offset	:=	Y offset from geometric center of image to central ray of the beam (required for DRR's where central ray is not in geometric center of pixel image)
Film Source	:=	FILM, ONLINE, COMPUTED
Unit Number	:=	Unit number film image acquired from
OD Scale	:=	Scale factor to convert pixel values to optical density
Bits per Pixel	:=	number of bits actually used for pixel information
Collimator Angle	:=	collimator angle in degrees (reflects the collimator angle for the associated beam) if the edges of the image are parallel to the collimator edges. This is **required only for DRR's** which are aligned with the collimator edges and which do not have the portal outline superimposed on the DRR image. It is not required for DRR's which are aligned with the unrotated collimator or for digitized films or on-line images (SIMULATOR and/or PORT images).

Format of data in the image file:

Binary Data

9.2 Sample Entries in the Directory

Image #	:=	37
Image Type	:=	DIGITAL FILM

```
Case #                  :=    1
Patient Name            :=    Joe Smith
Beam #                  :=    6
Beam Description        :=    Left Lateral Beam
Film Date               :=    15,11,1993
Film Number             :=    1
Film Type               :=    SIMULATOR
Number of Dimensions    :=    2
Size of Dimension 1     :=    480
Size of Dimension 2     :=    512
Grid 1 Units            :=    0.215
Grid 2 Units            :=    0.200
Source Image Distance   :=    140.0
X Offset                :=    0.0
Y Offset                :=    2.3
Number Representation   :=    TWO'S COMPLEMENT INTEGER
Bytes per Pixel         :=    2
Film Description        :=    verification simulation film
Film Source             :=    FILM

Image #                 :=    38
Image Type              :=    DIGITAL FILM
Case #                  :=    1
Patient Name            :=    Joe Smith
Beam #                  :=    6
Beam Description        :=    Right Lateral Beam
Film Date               :=    15,11,1993
Film Number             :=    2
Film Type               :=    SIMULATOR
Number of Dimensions    :=    2
Size of Dimension 1     :=    480
Size of Dimension 2     :=    512
Grid 1 Units            :=    0.215
Grid 2 Units            :=    0.200
Source Image Distance   :=    140.0
X Offset                :=    0.0
Y Offset                :=    2.3
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Film Description        :=    first day port image
Film Source             :=    ONLINE

Image #                 :=    39
Image Type              :=    DIGITAL FILM
Case #                  :=    1
Patient Name            :=    Joe Smith
Film Description        :=    AP Isocenter
Film Date               :=    15,11,1993
Film Number             :=    1
Film Type               :=    SIMULATOR
Number of Dimensions    :=    2
Size of Dimension 1     :=    640
Size of Dimension 2     :=    752
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Film Source             :=    FILM
```

9.3 Sample Image of Data for Digital Films

Data may be in 16-bit, 2's complement, integer representation wherein the 2's complement is never really used as the values are required to be in the range of 0 to 32767. The pixel data may also be in

unsigned byte data in which case the pixel values are between 0 and 255. Data is in raster order with the first pixel being the upper left-hand pixel in the image.

10. DOSE DISTRIBUTIONS

A dose distribution is the result of a calculation of dose at one or more points throughout the patient, for a particular configuration of beams - that is, for a particular "plan". Although in general, one might calculate doses on a completely irregular grid of points this is rarely done in practice and the proposed format is for a fairly regular grid, namely one in which a two dimensional array of points is defined in one or more parallel planes. This format naturally accommodates the computation of doses on a 2-D array of points in each CT scan, and recognizes that such scans may not be at equally spaced intervals. It permits the transfer of dose calculations throughout a volume, or in a single plane - or, indeed, along a line or at a single point. Planes may be other than parallel with the scan sections however, thus supporting calculations in sagittal or coronal planes. At present planes oblique to the major axes of the scans, or arbitrarily located points of calculation are not supported.

The points at which the doses are defined are assigned coordinates within the Patient Coordinate System. We first describe the coordinate definitions for the case of arrays defined in planes parallel to transverse sections (i.e. CT scans), and then indicate some differences when the planes are sagittal or coronal. The number of planes (>=1) and a list of the z-values is specified. Within a plane a rectangular array of points is defined by specifying the x, y coordinates of the upper left hand corner point (as viewed from the patient's feet), the x and y increments per point, and the number of points along the x-axis and along the y-axis. The z values for each plane may be unequally spaced and are therefor individually specified. For transverse planes these z values would normally be identical to those of some or all of the CT sections, but this is not required. The order of the planes should be that of increasing value of z.

To preserve the integrity of the right-handed cartesian coordinate system, some sign conventions **must** be obeyed when sagittal or coronal planes are used. The coordinates for single planes as presented to the observer are as follows:

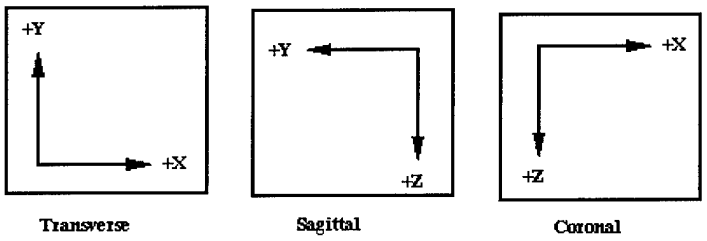


Figure 10.1

These sign conventions have implications for the various parameters as follows:

PARAMETER	TRANS.	SAG.	COR.
(Horiz, vert) coords of points	x, y	z, y	x, z
Usual signs of coords of ULH corner	-, +	+, +	-, -
Usual sign of horizontal increment	+	-	+
Usual sign of vertical increment			

Usual sign of vertical increment	-	-	+
Coordinate associated with plane change	z	x	y

Note that these conventions need not be obeyed in the definition of pixel size of CT scans. The vertical size is permitted to be positive for CT scans to conform to conventional usage and is interpreted as the absolute value of the pixel height, rather than a signed increment.

The units in which doses are given are up to the originator of the data. They must be in absolute dose units such as Gray. Relative and Percent are no longer supported in the Dose Units keyword and are now implicit by the inclusion of the Dose Scale keyword, where the Dose Scale keyword is used only if scaling is necessary. The dose values in the image file are multiplied by the Dose Scale value to obtain the Dose Units specified. A 1.00 is assumed for the Dose Scale value unless it is explicitly stated with the Dose Scale keyword.

Dose distributions other than Physical dose, such as of Effective dose, LET, OER or dose uncertainty, are supported through the use of the "Dose Type" keyword.

The Fraction Group ID allows multiple dose distributions to be submitted which will allow for fractionation information to be extracted for both targets and normal tissues. All beams contributing dose to this distribution shall have an identical Fraction Group ID in their beam geometry specification.

TEXT (ASCII) DOSE SPECIFICATION

The data storage in a dose image is "defined" through the example given in Section 10.3. The data are placed in the buffer in the following order:

Number of planes (e.g. 19)
Z-coordinate of first constant z plane (for e.g. z = -120.556)
A sequence of real numbers representing the dose at each grid point at this z value. X value (dimension 1) varies faster:

```
 0.000,    0.000,    0.000,    0.000,    0.000,    0.000,    0.000
 4.641,   11.785,   12.031,   10.608,   10.324,   10.258,   10.202
10.139,   10.125,   10.125,   10.118,    0.000,    0.000,   10.117
10.132,   10.148,   10.145,   10.145,   10.151,   10.183,   10.234
```

Z-coordinate of second constant z plane (for e.g. z = -119.616)
A sequence of real numbers representing the dose at each grid point at this z value. X value (dimension 1) varies faster:

```
 0.000,    0.000,    0.000,    0.000,    0.000,    0.000,    0.000
 2.011,    9.881,   11.476,   10.608,   10.324,   10.258,   10.202
10.139,   10.125,   10.125,   10.118,    0.000,    0.000,   10.117
```

BINARY DOSE SPECIFICATION

Doses may also be conveyed in a more succinct, binary format. In order to facilitate this format several additional (otherwise optional) keywords must be specified. Doses using the binary format must meet the following requirements:

must meet the following requirements:

- axial dose plane spacing (along Z axist) must be uniform
- the dose values are in two's complement integer format restricted to the positive domain (same as CT pixel values)
- the DOSE SCALE keyword must be used with the appropriate value stated which yields the appropriate dose values (with units) when the matrix values are multiplied by the DOSE SCALE value
- the COORD 3 OF FIRST POINT and DEPTH GRID INTERVAL keywords specifying the smallest (or most negative) Z coordinate and the step between each of the SIZE DIMENSION 3 planes must be specified

The optional keywords required for binary dose specification may not be usedwith text dose specification. The order of the dose matrix elements is identical to that used for the text representation excepting that the Z coordinate is no longer specified (nor is the plane count). As with all binary files, no text is supported in the file (e.g. comments in quotes).

10.1 Keywords for Images Used in Directory

Required Keywords

```
Image #                      :=   actual image (file) number (see 4.4)
Image Type                   :=   DOSE
Case #                       :=   1 for first patient, 2 for second
                                  patient, etc
Patient Name                 :=   patient identifier

Dose #                       :=   # identifying this distribution
Dose Type                    :=   PHYSICAL, EFFECTIVE, LET, OER, ERROR
Dose Units                   :=   GRAYS, RADS, CGYS
Orientation of Dose          :=   TRANSVERSE
Number Representation        :=   CHARACTER
Number of Dimensions         :=   3
Size of dimension 1          :=   # horizontal points (>=1)
Size of dimension 2          :=   # vertical points (>=1)
Size of dimension 3          :=   # of planes (>=1)
Coord 1 of first point       :=   x coord (cm) for transverse, etc.
Coord 2 of first point       :=   y coord (cm) for transverse, etc.
Horizontal grid interval     :=   delta-x (cm) for transverse (>0)
Vertical grid interval       :=   delta-y (cm) for transverse (<0)
```

Optional Keywords

```
Unit #                       :=
Writer                       :=
Date written                 :=   date (DD, MM, YYYY)
Dose description             :=   free text
Dose edition                 :=
Plan # of origin             :=
Plan edition of origin       :=
Study # of origin            :=
Version # of program         :=   planning program identification
x coord of normalizn point   :=   cm
y coord of normalizn point   :=   cm
z coord of normalizn point   :=   cm
Dose at normalizn point      :=   should result in units specified
                                  above after being multiplied by
```

```
                                    the Dose Scale
Dose error                  :=      NOMINAL, MINIMUM, or MAXIMUM
                                    (for dose range submissions)
Fraction Group ID           :=      ID grouping beams of common
                                    fraction for the doses in this
                                    image file
Number of Tx                :=      Number of times this fraction
                                    (Fraction Group ID) treated to
                                    achieve total doses in this file
Dose Scale                  :=      Scale factor to convert doses in
                                    image file to absolute doses in
                                    the units specified in the Dose Units.
                                    (assumed to be 1.00 if not specified)
Coord 3 of first point      :=      z coord (cm) for first transverse plane
Depth grid interval         :=      delta-z (cm) between each subsequent
                                    transverse dose plane (>0)
```

All coordinates and differences are expressed in centimeters in the patient coordinate system.

Format of data in the image:

ASCII text.

10.2 Sample Entries in the Directory

```
Image #                     :=      57
Image Type                  :=      DOSE
Case #                      :=      1
Patient Name                :=      CHEST1C
Dose #                      :=      1
Dose Type                   :=      PHYSICAL
Dose Units                  :=      GRAYS
Orientation of Dose         :=      TRANSVERSE
Number Representation       :=      CHARACTER
Number of Dimensions        :=      3
Size of dimension 1         :=      116
Size of dimension 2         :=      74
Size of dimension 3         :=      101
Coord 1 of first point      :=      -19.3000
Coord 2 of first point      :=      14.3000
Horizontal grid interval    :=      0.3000
Vertical grid interval      :=      -0.3000
Dose description            :=      4FLD CHESTWALL WITH BOLUS
Plan # of origin            :=      26
Fraction Group ID           :=      1
Number of Tx                :=      25
Dose Scale                  :=      0.01
```

10.3 Sample Image of Text Data for Dose

```
"Number of planes is "  101
"Z-coordinate is  " -15.200
   0.000,  0.000,  0.000,  0.000,  0.012,  0.012,  0.013,  0.013
   0.014,  0.015,  0.016,  0.016,  0.017,  0.018,  0.019,  0.019
   0.020,  0.021,  0.022,  0.022,  0.023,  0.024,  0.024,  0.025
   0.026,  0.026,  0.027,  0.028,  0.028,  0.029,  0.029,  0.030
   0.030,  0.031,  0.031,  0.032,  0.032,  0.032,  0.033,  0.033
   0.033,  0.033,  0.033,  0.033,  0.033,  0.033,  0.033,  0.033
   0.033,  0.032,  0.032,  0.032,  0.031,  0.031,  0.031,  0.030
     .       .       .       .       .       .       .       .
```

```
      .       .       .       .       .       .       .       .
      .       .       .       .       .       .       .       .
   0.030,  0.029,  0.029,  0.028,  0.027,  0.027,  0.026,  0.026
   0.025,  0.024,  0.024,  0.023,  0.022,  0.021,  0.021,  0.020
   0.019,  0.018,  0.018,  0.017,  0.016,  0.015,  0.014,  0.014
"Z-coordinate is  " -15.000
   0.013,  0.013,  0.012,  0.012,  0.011,  0.011,  0.011,  0.010
   0.010,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
   0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
      .       .       .       .       .       .       .       .
      .       .       .       .       .       .       .       .
      .       .       .       .       .       .       .       .
   0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
   0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
   0.012,  0.012,  0.013,  0.013,  0.014,  0.015,  0.015,  0.016
   0.017,  0.018,  0.019,  0.019,  0.020,  0.021,  0.022,  0.022
   0.023,  0.024,  0.024,  0.025,  0.026,  0.026,  0.027,  0.027
```

10.4 Sample Image of Binary Data for Dose

ADD6: The data file for binary formatted dose data consists of two byte integer values restricted to the values from 0 to 32767 packed with the most significant byte first (identical to the numeric format used for CT scans) written in raster order for each axial dose plane. Each subsequent axial plane's dose values are required to be in order of increasing Z coordinate. Any padding required for buffering (for tape writing only) is required only after the last dose point of the last axial plane is written to the file.

---

11. DOSE-VOLUME HISTOGRAMS

Dose-volume histograms (DVH) provide a "pre-digestion" of the doses provided in a 3-D dose distribution with corresponding anatomic structures. While there are several different methods which may be used to display the DVH data, the underlying data is the same: A bin of dose range and a volume associated with the dose range. DVH's are transferred as one structure per image file.

The data in the image file itself is simply an array of doublets where the first value in the doublet is the lower end of the dose bin and the second value is the volume associated with the dose bin. The doses may be in either absolute dose or percent dose and may be converted back and forth using directory information. The volume may be in units of percent or of cubic centimeter (cc) and may be converted back and forth with the additional information available in the directory information for the image file. The dose bins are required to be uniformly spaced and included in the data file from zero dose to the highest dose for which any non-zero volume is identified and no gaps are allowed.

The scaling of relative or percent doses or volumes are performed by multiplying the relative dose or volume value by the appropriate scale value.

11.1 Keywords for Dose-Volume Histograms Used in Directory

Required Keywords

```
Image #                 :=   actual image (file) number (see 4.4)
Image Type              :=   DOSE VOLUME HISTOGRAM
Case #                  :=   1 for first case, 2 for second case
```

```
                                  in file set
Patient Name                :=    Patient Identifier

Structure Name              :=    name of structure
Dose Units                  :=    GRAYS, CGYS, RADS
Dose Type                   :=    ABSOLUTE, PERCENT, RELATIVE
Volume Type                 :=    ABSOLUTE, PERCENT, RELATIVE
Number of Pairs             :=    Number of dose/volume pairs in image
                                  file
Maximum # Pairs             :=    Maximum number of dose/volume pairs
                                  allowed
Number Representation       :=    CHARACTER
Plan ID of Origin           :=    ID of plan DVH's calculated from.
                                  Indexes with beams and dose
                                  distributions.
```

Optional Keywords

```
Dose Scale                  :=    Scales percent or relative dose to
                                  absolute dose (Required if dose type
                                  is not ABSOLUTE)
Volume Scale                :=    Scales percent or relative volume
                                  to cc's (Required if volume type is
                                  not ABSOLUTE)
Date of DVH                 :=    Date DVH calculated (DD, MM, YYYY)
```

Format of data in the image file:

ASCII TEXT

11.2 Example of Dose-Volume Histogram Directory Entries

```
Image #                     :=    39
Image Type                  :=    DOSE VOLUME HISTOGRAM
Case #                      :=    1
Patient Name                :=    Joe Smith
Structure Name              :=    Rectum
Plan ID of Origin           :=    final
Dose Units                  :=    GRAYS
Dose Type                   :=    ABSOLUTE
Volume Type                 :=    RELATIVE
Volume Scale                :=    203.1
Number of Pairs             :=    100
Maximum # Pairs             :=    1001
Number Representation       :=    CHARACTER
Date of DVH                 :=    15,11,1993

Image #                     :=    40
Image Type                  :=    DOSE VOLUME HISTOGRAM
Case #                      :=    1
Patient Name                :=    Joe Smith
Structure Name              :=    PTV
Plan ID of Origin           :=    final
Dose Units                  :=    GRAYS
Dose Type                   :=    ABSOLUTE
Volume Type                 :=    RELATIVE
Volume Scale                :=    203.1
Number of Pairs             :=    100
Maximum # Pairs             :=    1001
Number Representation       :=    CHARACTER
Date of DVH                 :=    15,11,1993
```

```
Date of DVH              :=    15,11,1993
```

11.3 Example of Dose-Volume Histogram Image File

```
"Minimum Bin Dose,  Fractional Volume"
  0.00, 0.05
  1.00, 0.00
  2.00, 0.06
    . . . .
    . . . .
    . . . .
100.00, 0.00
```

Note that the volume associated with each bin dose is that volume which explicitly falls into that dose bin (hence the zero volume values for 1.00 Gy above sandwiched between the 0.00 Gy and 2.00 Gy bins.

---

12. SEED GEOMETRY

Seed geometry files are used to convey the geometric distribution of permanently implanted I125 or Pd103 seeds. These seed distributions may be indexed with an image data set (CT, MRI or Ultrasound), or may be independent of any image set. The information provided in this file should be adequate to calculate the dose distribution with minimal modification of the incoming data by the receiving institution. Multiple seed distributions are supported in a single file set through the use of unique plan identifiers contained in the directory file. This will facilitate pre-implant and post-implant plans in the same file set.

The fundamental information contained in the directory entries for a Seed Geometry file are:

- Free text identification of the seed model and/or manufacturer to be able to distinguish between the differing characteristics of seeds of various manufacture;
- The isotope for the seeds (restricted to I125 or PD103 for this version of the exchange;
- The strength of the seeds on the day of implant (all seeds are expected to have the same activity +/- the deviation of the batch;
- The units of seed strength specified;
- The date of the implant;
- The number of seeds in the implant (note that these numbers may differ from pre-plan to post-plan);
- A plan ID string to differentiate pre- and post-plans; and
- Indication of which images in the file set (if any) with which the coordinates of the seeds register.

The data file associated with the directory entries consists of only coordinate triplets (in cm) for each of the number of seeds specified in ASCII (text) format.

12.1 Keywords for Seed Geometry Used in Directory

Required Keywords

```
Image #                  :=   actual image (file) number (see 4.4)
```

```
Image Type              :=   SEED GEOMETRY
Case #                  :=   1 (or registered case number)
Patient Name            :=   Patient Identifier

Seed Model              :=   model identifier or manufacturer of seed
Isotope                 :=   I125 or PD103
Seed Strength           :=   value corresponding to strength units specified
Strength Units          :=   MCI or CGYCM2PERHR
Date of Implant         :=   date (DD, MM, YYYY)
Number of Seeds         :=   Number of seeds in image file (implant)
Number Representation   :=   CHARACTER (format of data in data file)
Plan ID of Origin       :=   ID of plan seed distribution from
                             Indexes with dose distributions.
```

Optional Keywords

```
Registered              :=   NONE, CT SCAN, MRI or ULTRASOUND
                             (must be specified if seed coordinates are
                             registered with any of the above image sets)
                             NONE is assumed if this keyword is not used.
```

Format of data in the image file:

ASCII TEXT

12.2 Example of Seed Geometry Directory Entries

```
Image #                 :=   42
Image Type              :=   SEED GEOMETRY
Case #                  :=   1
Patient Name            :=   Joe Smith

Seed Model              :=   6711
Isotope                 :=   I125
Seed Strength           :=   0.43
Strength Units          :=   MCI
Date of Implant         :=   23, 06, 1999
Number of Seeds         :=   85
Number Representation   :=   CHARACTER
Plan ID of Origin       :=   Preplan
```

```
Image #                 :=   44
Image Type              :=   SEED GEOMETRY
Case #                  :=   1
Patient Name            :=   Joe Smith
Seed Model              :=   6711
Isotope                 :=   I125
Seed Strength           :=   0.43
Strength Units          :=   MCI
Date of Implant         :=   23, 06, 1999
Number of Seeds         :=   83
Number Representation   :=   CHARACTER
Plan ID of Origin       :=   Actual Plan
Registered              :=   CT SCAN
```

12.3 Example of Seed Geometry Image File

```
"          X (cm),  Y (cm),  Z (cm)"
"Seed #1"    0.00,    0.05,    5.00
"Seed #2"    0.00,    0.05,    5.90
"Seed #3"    0.00,    0.05,    7.20
"Seed #4"    0.00,    0.05,    8.10
   . . . .
   . . . . (intervening 80 seeds not shown)
   . . . .
"Seed #85"    3.00,    3.25,   4.70
```

Document maintained by William B. Harms, Sr. and Walter R. Bosch

Last modified: 09/10/1999 15:25:35

Appendix 2

RTOG Permanent Prostate Brachytherapy Quality Assurance Guidelines

I. Purpose:

A. To establish quality assurance (QA) guidelines for the conduct of low dose rate, permanent prostate brachytherapy for the purpose of performing national, multi institutional cooperative studies.

II. Background

A. Preliminary reports of the success of transperineal, interstitial permanent prostate implants (TIPPB) in controlling early stage prostate cancer with few complications have heightened the interest of the medical community. Controlled, prospective multi-institutional trials to validate and investigate the efficacy of this procedure have become a goal of the RTOG. The 3DQA center has expanded its mission to insure the scientific soundness of these trials. The 3DQA Center performs this function through (1) individual and institutional credentialing, (2) establishment of procedural standards, and (3) centralized quality assurance review of case submissions.

B. A partial list of references that describe the procedure and appropriate quality assurance for prostate implantation are listed below.

1. Blasko, JC, et al. Brachytherapy and organ preservation in the management of carcinoma of the prostate. Sem. Radiat. Oncol. 3:240-249, 1993.

2. Grimm, PD, et al. Ultrasound-guided transperineal implantation of iodine125 and palladium-103 for the treatment of early stage prostate cancer; technical concepts in planning, operative technique and evaluation. Atlas Urol. Clin. North Am. 2:113-125, 1994.

3. Wallner, K, et al. Dosimetry guidelines to minimize urethral and rectal morbidity following transperineal I-125 prostate brachytherapy. Int J Radiat Oncol Biol Phys, 32:465-471, 1995.

4. Stock, RG, et al. A dose response study for I-125 prostate implants. Int J Radiat Oncol Biol Phys, 41:101-108, 1998.

5. Prestidge, BR, et al. Timing of computed tomography-based post-implant assessment following permanent transperineal prostate brachytherapy. Int J Radiat Oncol Biol Phys, 40:1111-1115, 1998.

6. Bice, WS, et al. Centralized multi-institutional post-implant analysis for interstitial prostate brachytherapy. Int J Radiat Oncol Biol Phys, 41:921 927, 1998.

7. Nath, R. et al. Code of practice for brachytherapy physics: report of the AAPM Radiation Therapy Committee Task Group No. 56. Med Phys 24:1557-1598, 1997.

8. Nath, R, et al. Dosimetry of interstitial brachytherapy sources: recommendations of the AAPM Radiation Therapy Committee Task Group No. 43. Med Phys 22(2):209-234, 1995.

9. Nag, S, et al. American Brachytherapy Society (ABS) recommendations for transperineal permanent brachytherapy of prostate cancer, Int J Radiat Oncol Biol Phys, 44(4):789-799, 1999.

III. Credentialing

A. General: Brachytherapy, by its nature, is dependent upon the skill of the brachytherapist and the expertise of the support staff. Credentialing therefore needs to address the qualifications and efforts of the implant team as well as the type and quality of available equipment. A credentialing questionnaire is available via the 3D QA Center's web site (http://rtog3dqa.wustl.edu).

B. Equipment

1. Imaging: If ultrasound, fluoroscopy, CT or MRI is used to perform prostate implants, the institution is asked to explain how the imaging capability of the equipment was determined and what regularly scheduled procedures are in place to insure that the equipment continues to meet stated specifications.

2. Treatment Planning: Information pertaining to the system used for pre and post implant planning and evaluation is listed on the credentialing questionnaire. Capabilities and the use of the system in the conduct of the procedure should be detailed, as well as the routine QA tests performed to insure the proper functioning of the treatment planning system (TPS). The method of conducting a second check of the calculations performed by the TPS should be provided.

3. Sources: The questionnaire queries the type, form and range of nominal strengths for sources used for prostate implantation. Additionally, the procedures used to insure the receipt and implantation of the proper sources (e.g., assay and handling procedures) should be provided. Assay procedures and regular quality control of the assay equipment will be addressed.

C. Procedures

1. Protocols: Written protocols that describe the implant procedure shall be attached to the questionnaire. These protocols should address, as a

minimum, patient selection and flow, procedural scheduling and conduct, source procurement and handling, record keeping and safety procedures.

2. Design Methods: Implant design procedures will be addressed, whether the implants are individually designed prior to the implant or the implants are performed according to a set of rules developed for all cases and modified individually in the operating room. The method of delineating the gross tumor volume (GTV), the clinical target volume (CTV) and the planning target volume (PTV) needs to be provided as well as any regular deviations from the plan (e.g., the insertion of extra sources).

D. Individual Qualifications: The training and experience of the implant team is of paramount importance in the performance of a quality implant and is addressed in the questionnaire.

1. Radiation Oncologist.

2. Urologist

3. Medical Physicist

4. Dosimetrist

5. Ultrasonographer

6. Any other personnel that the brachytherapist feels might materially affect the quality of the implant.

IV. Procedural Standards

A. The institution should have a written protocol outlining the normal conduct of the implant procedure. This protocol should address, as a minimum, order, receipt, inventory, handling and disposal of radioactive sources; patient selection, scheduling, and flow; procedural conduct and record keeping.

B. Preplanning should be performed individually on a treatment planning system or via a standard, published implant rules (a nomogram with distribution rules, for instance). Prior to the beginning of the implant procedure, each member of the implant team must have access to the following written information: patient demographic data, disease specifics, size and location of the GTV, CTV and PTV, the type, strength, and number of sources that will be implanted and their planned location, the targeted dosimetric result of the implant, e.g., the reference dose and the design intent to deliver at least this dose to the PTV.

C. Every patient will have post implant dosimetry performed. As a minimum, this evaluation will include target localization, a dosimetric

display that is based upon this target location and a method of quantifying the dosimetric data that enables meaningful comparison and tracking of results. Normally this quantification will occur via the generation of a Dose Volume Histogram (DVH). The post plan should be generated within 30 days of the implant procedure.

D. A representative sample of the sources will be assayed to verify the vendor's stated source strength. An acceptable result is obtained when the average strength of the assayed sources is within $\pm$5% of the stated strength.

E. A method of independently checking the results of the treatment plan is required prior to performing the implant. Comparison with similar, previous implants via an institutionally developed gland size versus total air kerma strength curve is acceptable.

F. Specific equipment standards

1. Ultrasound (Frequencies, axial and lateral resolution, low contrast detectability, noise)

2. Fluoroscopy (Resolution, contrast, noise, dose)

3. CT (Resolution, contrast, noise, dose)

4. MRI (Resolution, contrast, noise)

5. Assay equipment

a. NIST-traceable calibration once every year either by an ADCL or a vendor-calibrated source.

b. Sensitivity sufficient to distinguish differences of one part in 100.

c. If the assay is to be used for calibration of sources as opposed to quality assurance (i.e., the assay source strength is used for planning, as opposed to that stated by the manufacturer), the system must meet the qualifications for a dose calibrator (e.g., linearity and reproducibility).

G. Implant standards. Implants may be adjudged as having no deviation, minor deviation or major deviation based upon the dosimetric analysis provided by the post implant evaluation treatment plan.

V. Case Submissions

A. Each case submitted to the quality assurance center will have the following items attached.

1. A pre-implant treatment plan, if one is performed. The pre-implant treatment plan will consist of at least the following.

a. The volume study upon which the treatment plan was based. Images and associated contours must be submitted in a 3D QA Center approved digital format. Each image will have the GTV and/or CTV contoured on it, if applicable.

b. The dose distributions (for each set of identical activity and model seeds intended to be used) must be submitted in a 3D QA Center approved digital format.

c. Hard copy isodoses showing the intended target volume with isodose lines superimposed on the volume study image set will be provided for at least three transverse cuts (one each near the superior and inferior periphery of the CTV and one near the center) in such a fashion as to be able to determine the extent of the isodose surface and its relationship to the target and surrounding anatomy. Isodose lines may be normalized to some value (e.g., the reference dose) or displayed in dose, but will include at least the following values with relation to the prescription (reference) dose.

(1) 200%

(2) 150%

(3) 100%

(4) 80%

(5) 50%

d. The seed localization information must be submitted in a 3D QA Center approved digital format for each model and activity of seed used in the pre-implant treatment plan.

e. A copy of the physician's prescription.

2. A copy of the implant records will be provided showing the final number of sources implanted. The implant records must also reflect any deviation from either the pre plan or, for those patients implanted with a nomogram and implant rules, the template locations, spacing and quantity of sources used for each needle.

3. A post-implant treatment plan which is used to evaluate the quality of the implant. The post-implant treatment plan will consist of the following.

a. A copy of any image set (CT, MRI or ultrasound) used to develop the treatment plan as well as the appropriate contours on each image cut must be submitted in a 3D QA Center approved digital format. If plane films are used to determine source

placement or to verify the total source count, copies of these films is required (or a digital equivalent in a approved digital format). Post implant dosimetry based solely upon plane films is considered inadequate, as the location of the target cannot be derived from plane films. Each submitted image set shall have the following structures delineated on each image, if applicable.

(1) GTV (Prostate)

(2) Urethra

(3) Rectum

b. The dose distributions (for each set of identical activity and model seeds intended to be used) must be submitted in a 3D QA Center approved digital format.

c. Hard copy isodoses showing the target volume with isodose lines superimposed on the volume study image set will be provided for at least three transverse cuts (one each near the superior and inferior periphery of the CTV and one near the center) in such a fashion as to be able to determine the extent of the isodose surface and its relationship to the target and surrounding anatomy. Isodose lines may be normalized to some value (e.g., the reference dose) or displayed in dose, but will include at least the following values with relation to the prescription (reference) dose.

(1) 200%

(2) 150%

(3) 100%

(4) 80%

(5) 50%

d. The seed localization information must be submitted in a 3D QA Center approved digital format for each model and activity of seed used in the implant.

e. Dose volume histogram showing the distribution of dose within the GTV (Prostate). This may be submitted electronically and must be submitted in tabular format (10 Gy bins, 10 - 400 Gy)

f. A copy of the physician's prescription.

B The above items will be submitted within two weeks after the post-implant imaging procedure (CT or MRI) as specified by protocol.

VI. Centralized Quality Assurance Review

A. The centralized quality assurance review will be generated and a report issued to the submitting institution within 30 days of receipt of all required materials and data.

B. The report will consist of at least the following.

1. An analytical evaluation of the delineation of the GTV, the CTV, the urethra and the rectum.

2. Isodose displays in accordance with paragraph V.A. 1 .c.

3. A dose volume histogram of the prostate, a dose surface histogram of the rectum and the urethra, and a dose profile or trace along the center of the urethra. Quantifiers associated with the DVH shall also be provided.

a. V_{xxx} - the volume of the prostate included within the surface defined by xxx% of the reference dose. The values for xxx shall be 200, 150, 100 and 80, i.e., V_{200}, V_{150}, etc.

b. D_{xxx} - the dose which defines a surface within the prostate which encompasses xxx% of the prostate volume. . The values for xxx shall be 100, 90 and 80, i.e., D_{100} D_{90}, etc. D_{100} is also known as the minimum peripheral dose (mPD)

c. The maximum dose to the urethra and the rectal surface. That surface area of the urethra, which receives more than 250 Gy, and the surface area of the rectum, which receives more than 100 Gy. The linear length of the urethra, which receives more than 250 Gy.

d. The target volume ratio (TVR) of the dose distribution. The target volume ratio shall be calculated as the volume encompassed by the reference isodose surface divided by the volume of prostate. A modified TVR shall also be provided which is defined as the volume encompassed by the reference isodose surface divided by V_{100}.

4. A comparative evaluation of the implant with all other implants in the database in terms of the quantifiers listed above.

Permanent Prostate Brachytherapy QA Facility Questionnaire

Please type this form.

ITEMS REQUIRED BEFORE YOU CAN ENTER CASES ON EACH RTOG TIPPB PROTOCOL:

- Acquire this Facility Questionnaire document from http://rtog3dqa.wustl.edu contemporaneously with completing it and forward the completed form with all required attachments and the requisite Dry Run test data for each prostate brachytherapy protocol you wish to become qualified to participate in to:

  James A. Purdy, Ph.D.
  RTOG 3D Quality Assurance Center
  Washington University
  510 S. Kingshighway Blvd.
  St. Louis, MO 63110

- Demonstrate capability of digital data exchange with the RTOG 3D QA Center and understanding of protocol requirements via the Protocol specific Dry Run Test including (see protocol specific Dry Run Guide published on the 3D QA Center's web site at http://rtog3dqa.wustl.edu):
  1. Patient CT data
  2. Patient Ultrasound data
  3. Contours – critical normal structures and protocol required gross tumor volume(s) (GTV), clinical target volume(s) (CTV) and planning target volume(s) (PTV).
  4. 3D dose distribution data.
  5. Source type, seed model, source strength, and position.
  6. Dose-volume histograms for plan.
  7. Axial, sagittal and coronal hard copy isodoses through center of GTV (in absolute dose).
  8. Protocol specific Dry Run T2 Form (different from standard T2 form, available only from 3D QA Center's web site).

- If you intend to submit your digital patient data via the internet, please contact Mr. William Harms at (314) 362-2648 to establish an ftp account for your facility on the 3D QA Center's ftp server (castor.wustl.edu).

I. General Information

Please complete this questionnaire and submit it and the requested supporting physics and dosimetry documents to the RTOG 3D QA Center for each prostate brachytherapy protocol you wish to become qualified to participate in. These data will help assure the RTOG 3D QA Center that each institution has committed proper facilities and effort to this modality.

In addition to this documentation, a protocol specific Dry Run test must be successfully completed to qualify for each study. The Dry Run test should be concurrently developed with the completion of this Questionnaire to facilitate your qualification to participate in the selected protocol. The protocol specific Dry Run Guidelines must be obtained from the RTOG 3D QA Center's Web site (http://rtog3dqa.wustl.edu).

RTOG Protocol #: _____ **RTOG Institution #:** _____

If Affiliate, Name of Member Institution: _____

Responsible Radiation Oncologist

Name: _____

Address: _____

_____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Urologist

Name: _____

Address: _____

_____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Medical Physicist

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Dosimtrist

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Ultrasonographer

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Research Associate (Data Manager)

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

II. Experience of personnel:

A. How many ultrasound guided prostate implants have been performed by the above named radiation oncologist: _____

B. Over what time period has this experience been gained: _____ years _____ months

C. How many ultrasound guided prostate implants have been preplanned by ultrasound and evaluated with a post implant CT, by the above named physicist: _____

D. Over what time period has this experience been gained: _____ years _____ months

III. TIPPB Equipment (to be used for protocol patients)

A. Ultrasound Unit

1. Vendor/Model:

B. CT Scanner

1. Vendor/Model:

C. MR Scanner (optional)

1. Vendor/Model:

D. 3D Treatment Planning System

1. Vendor/Model:
2. If developed "in-house", please check ☐ and attach a description.
3. Do your ^{125}I dose calculations agree with TG-43 to within ±5% from 5-70 mm: Yes No
4. How are prostate and rectal contours entered? Preplan: ☐ videotaped ☐ digitized
   Postplan: ☐ CT based ☐ Hand entered
5. Confirm that the dose calculational matrix is no larger than 4 mm x 4 mm: ☐ Yes ☐ No
   Dose calculation matrix size is ____ mm x ____ mm.
6. How do you superimpose dose distributions on contours? By computer By hand
   If by hand; describe technique:_____
   _____
7. Dose Volume Histograms: ☐ By computer ☐ By hand

E. Sources

1. Source Type:	Vendor/Model:
2. Source Type:	Vendor/Model:

IV. Quality Assurance Procedures: (attach the following)

A. Source Strength Verification: Submit a description of the procedures followed to verify the calibration of the sources. Include the following:

- Description of dosimeter system (make and Model of chamber and electrometer)
- Confirmation of traceability to NIST
- QA procedures to verify calibration of dosimeter has not changed
- Measurement technique
- Calculation technique, including conversion of the above standard into the source specification units used by your treatment planning computer.
- Frequency of calibration

B. Source Accounting:

- Describe the procedures used to account for all seeds at the time of implant and to assure that the number implanted is used in the dose calculation.
- Also, discuss techniques used to avoid identifying the same source on multiple slices.

C. Dosimetry Procedures:

- Describe any hand calculations done to verify the accuracy of the computer generated treatment plan.
- Describe any other procedures followed to assure that the dose calculations are in accordance with the requirements of the protocol.

D. Imaging Procedures:

- Describe how the imaging capability of the equipment (ultrasound, fluoroscopy, CT or MRI) used to perform prostate implants was determined and what regularly scheduled procedures are in place to insure that the equipment continues to meet stated specifications.

E. Other QA Procedures:

- Describe any other quality assurance procedures pertinent to the study objectives.

RTOG Prostate Cancer Brachytherapy Research Group Meeting

Washington University School of Medicine, St. Louis, Missouri
6th fl. Barnard Hospital, Room 624
Monday, October 5, 1998

Agenda

10:15 Welcome/Opening Remarks
- *Jim Purdy, Ph.D.*

10:20 The RTOG 3DQA Center
- *Jim Purdy, Ph.D.*

10:45 Review of DOD Prostate Cancer Brachytherapy Research Proposal
- *Jim Purdy, Ph.D.*

11:00 Clinical Presentations
- *Bill McLaughlin, M.D.*
- *Brad Prestige, M.D.*
- *Jeff Michalski, M.D.*

12:00 Open Discussion Session

12:30 - 1:30 Lunch

1:30 Digital Data Exchange Standards For Multi-Institutional 3-D TIPPB Trials
- *Bill Harms, Sr., B.S.*

2:00 3-D Treatment Planning/Clinical Databases for Multi-Institutional 3-D TIPPB Clinical Trials
- *Walter R. Bosch, D.Sc..*

2:30 Automated Source Localization and Other QA Issues
- *Bill Bice, Ph.D.*

3:00 Open Discussion Session

4:30 Closing Remarks
- *Jim Purdy, Ph.D.*

MINUTES

RTOG/DOD Prostate Cancer Brachytherapy Research Group Meeting

Washington University School of Medicine, St. Louis, Missouri
Monday, October 5, 1998

Attendees: Jim Purdy, Ph.D. (Chair); William Bice, Ph.D.; Walter Bosch, D.Sc.; William Harms, B.S., John Matthews, D.Sc.; William McLaughlin, M.D.; Jeff Michalski, M.D.; Sasa Mutic, M.S.; Bradley Prestige, M.D.; Peter Roberson, Ph.D.; Jeffrey Williamson, Ph.D.

Dr. Purdy called the meeting to order at approximately 10:15 AM. Introductions were made and the agenda reviewed. Dr. Purdy made a presentation of the history and current activities of the RTOG 3D QA Center. He pointed out that the 3D QA Center was formed in 1992 and was charged to achieve the following specific aims:

- Define basic technical, quality assurance, and clinical guidelines necessary for participation in RTOG 3-D CRT protocols.
- Establish credentialing criteria for institution participation in RTOG 3-D CRT clinical trials.
- Develop a mechanism by which institutions would submit 3-D CRT treatment planning verification (TPV) data.
- Develop a QA review process of 3-D CRT TPV data.

Dr. Purdy proposed that we follow a similar approach for future RTOG 3-D image-based brachythrapy protocols. He reviewed the revised DOD grant proposal. He pointed out that RTOG 98-05 protocol, in which Dr. Colleen Lawton, M.D. is the Study Chair, is not a part of the revised grant application. The original grant application in which Dr. John Blasko, M.D. was the principal investigator included the RTOG 98-05 protocol. However, because of change in resources, Dr. Purdy replaced Dr. Blasko as the principal investigator and prepared a revised grant application that focused on the development of software tools and infrastructure to perform quality assurance reviews for future multi-institutional 3-D image-based transperineal interstitial permanent prostate brachytherapy (TIPPB) clinical trials. During the 30 month developmental period supported by DOD grant, the 3D QA Center would not provide any QA review of TIPPB studies and thus the RTOG 98-05 protocol was removed from the revised grant application.

Dr. Purdy reviewed the tasks to be accomplished in the 30 month period supported by the DOD grant as follows:

Task 1. Develop and evaluate analytical methods and tools for 3-D calculation and dose volume histogram evaluation of TIPPB.

Task 2. Establish a methodology for electronic data exchange of TPV data between institutions and the RTOG 3-D QA Center as well as a link to the RTOG Statistical Headquarters outcome database.

Task 3. Develop a program for providing centralized QA reviews of TPV data which would be submitted by participating institutions for patients receiving TIPPB as part of any future prospective, multi-institutional clinical trials.

Task 4. Develop guidelines for the credentialing of institutions enrolled in national prostate brachytherapy trials and establish standards for the performance of TIPPB.

Task 5. Develop a TPV database to be used in the correlation of implant quality with efficacy of tumor eradication and morbidity of the procedure.

Several clinical issues were discussed next. Dr. McLaughlin made a formal presentation reviewing several issues including prostate GTV definition, isotope selection, and pre and post-dosimetry issues. He also led the discussion on quantitating the definition of a "good" implant.

Dr. Prestige followed with a formal presentation addressing many of the same issues including target definition, target coverage, and timing of implant assessment. He pointed out that while 3-D CRT was driven by the academic radiation oncology groups, TIPPB has been driven primarily by the private sector and that future clinical trials may have to be more sensitive to concerns from that sector.

Dr. Michalski also made a formal presentation raising issues regarding how much of the pre-plan dosimetry should undergo QA review, CT quality (the current TIPPB planning systems apparently sample down the CT data providing poor image quality for defining the prostate GTV). There was considerable discussion as it was recognized that depending on the imaging study and its quality, (CT, spiral CT, MR, or, US) different volumes for the GTV could be defined.

Mr. Harms made a formal presentation describing the RTOG digital patient data exchange format being used for the on-going RTOG 3-D CRT clinical trials. This specification provides for participating institutions to submit (via either the Internet or magnetic tape) common format 3-D TPV data for QA review including: volumetric CT image data, normal structure, tumor and target volume contours, digitally reconstructed radiographs or digitized simulator (prescription) and portal radiographs, beam geometry, dose distributions, fractionation information, and dose-volume histograms. In order to provide data exchange of treatment planning data for TIPPB, the RTOG 3D QA Center will extend the currently functioning RTOG digital data exchange to include those data items required to adequately model the treatment modality. These extensions will, as a minimum, include the following data items: (1) Digital ultrasound images; (2) Magnetic resonance images; (3) Radioactive seeds localization and specification.

Dr. Bosch made a formal presentation describing the 3D QA Center's data model that has been used for the integrated TPV/clinical database for the 3-D CRT external beam clinical trails. We will extend our data model to represent brachytherapy sources using the DICOM-RT Plan Information Object Definition as a pattern. Multiple imaging modalities will also require minor modification of information entities representing CT images. Dr. Bosch also demonstrated the current status of some of the prototype WWW-based graphical review tools we are proposing to further develop to facilitate remote QA review from other locations of patient images, organ contours, and dose-volume histograms.

Dr. Bice made a formal presentation describing the technique for source localization from axial CT images that he has developed. Some form of automated source localization will be needed to be implemented on the 3D QA Center's review system. Dr. Bice also presented the recent study he published in the IJROBP, "Centralized Multiinstitutional Postimplant Analysis For Interstitial Prostate Brachytherapy," which was a pilot study that compared the results obtained from ^{125}I implants conducted at five different institutions.

The remaining parts of the meeting were devoted to an open discussion and developing individual work assignments. Specifically, the following assignments were made:

- Drs. Prestige and Bice were to develop a first draft of TIPPB QA Guidelines following the format of the RTOG 98-03 external beam QA guidelines available on the QA Center's Web Site.
- Drs. McLaughlin and Roberson were to develop a first draft of a TIPPB Questionnaire following the format of the RTOG external beam questionnaire available on the QA Center's Web Site.
- Mr. Harms was to develop a first draft of the new digital data exchange specification.
- Dr. Bosch will begin extending the data model to represent brachytherapy sources and the other imaging modalities pertinent to TIPPB.
- Dr. Matthews will begin implementing software to allow TIPPB dose calculation and display on a 3D QA review system.

There was general agreement that the next meeting of the group should be held at the RTOG meeting January 14-17, 1999 in Atlanta. Dr. Purdy will ask Ms. Nancy Smith to arrange meeting room, time and date.

With no further discussion, the meeting concluded at approximately 4:30 PM.